

PATIENT INFORMATION BOOKLET

Endovascular Stent Grafts:
A Treatment for
Abdominal Aortic Aneurysms

TABLE OF CONTENTS

Introduction	1
Glossary	2
Abdominal Aorta	4
Abdominal Aortic Aneurysm	5
Causes	6
Symptoms	6
Treatment Options	6
Open Surgery	7
Endovascular Stent Grafting	8
Abdominal Stent Graft	9
Risks	10
Benefits	11
Abdominal Stent Graft Procedure	12
What Symptoms Should Prompt You to Call Your Doctor After the Procedure?	14
Follow-Up	14
Implanted Device Identification Card	14
Magnetic Resonance Imaging	15
Lifestyle Changes	15
Questions You May Want to Discuss with Your Doctor	15
Additional Information	17

INTRODUCTION

You have discussed having a stent graft procedure to treat an **abdominal aortic** aneurysm (AAA) with your doctor. Your doctor has given you this guide to help you further understand the device and procedure. Only a doctor can determine if you are a good candidate for an abdominal **stent graft** procedure.

A Glossary is provided in the next section to help you understand the medical terms used in this book. Words that are bolded in the text are defined in the Glossary.

GLOSSARY

Abdominal aortic aneurysm (AAA): A bulging or “ballooning” of a weakened area of the abdominal aorta. This term is often called “AAA.”

Anatomy: The study of parts of the body.

Aneurysm rupture/Rupture: A tear in the blood vessel wall near or at the location of the weakened area of the blood vessel.

Aorta: The main artery that carries blood from the heart to the rest of the body.

CT scan: A scan that creates a series of X-rays that form a picture of the aneurysm and nearby blood vessels.

Endoleak: Blood flow into the aneurysm (bulge or ballooning of the weakened area of the blood vessel) after placement of a stent graft.

Endovascular: Inside or within a blood vessel.

Endovascular stent grafting: A procedure in which a tube-shaped device is placed inside a diseased vessel without surgically opening the tissue surrounding the diseased vessel.

Exclude: Shutting off or removing from the main part.

Femoral arteries: Blood vessels that carry blood to the thigh region of each leg. Doctors can use these arteries as pathways to reach the aorta.

Fluoroscopy: A real-time X-ray image that is viewed on a monitor. This is an imaging technique generally used by doctors to see the placement of the stent graft during endovascular procedures.

Imaging: The use of X-rays, CT scans, MRI scans or other techniques to obtain pictures of the inside of the body.

Minimally invasive: Involving a puncture or cut of the skin without exposing the internal organs.

Magnetic resonance imaging (MRI): A technique that uses magnetic fields to form images of structures within the body.

Open surgery/Open surgical repair: A type of surgery performed to repair an aneurysm. The doctor repairs the aorta by making a large cut in the abdomen. The weakened area of the aorta is removed and replaced with

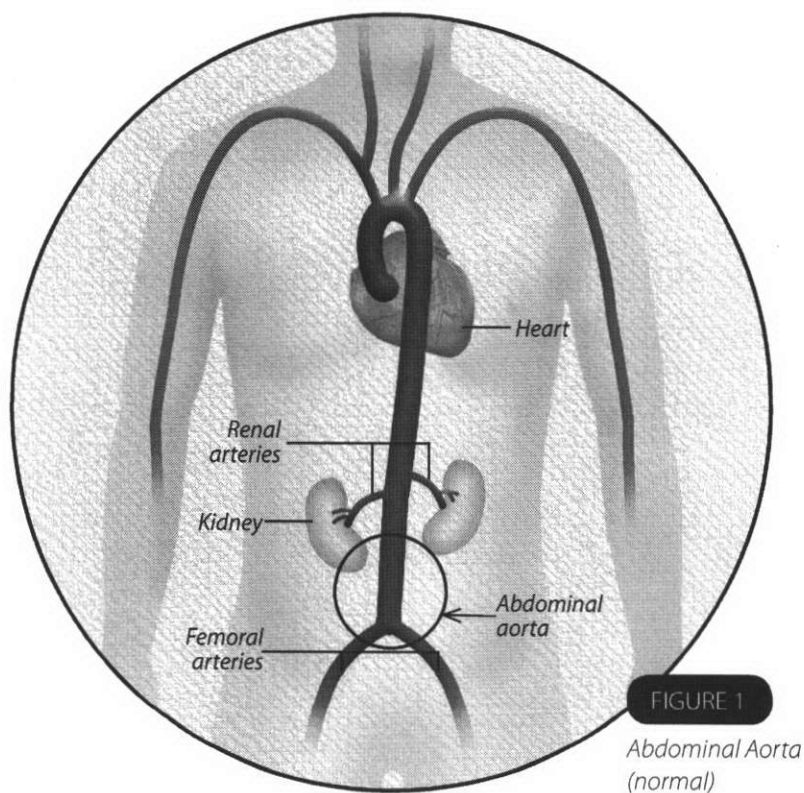
a fabric graft. The graft is sewn into place and acts as a replacement blood vessel.

Stent graft/Abdominal stent graft: A woven polyester tube supported by a tubular metal web that is placed inside of a diseased vessel without surgically opening the surrounding tissue. After being placed in the artery, the stent graft expands and relieves the pressure on the aneurysm by providing a new pathway for blood flow.

Ultrasound: An imaging technique that creates an image through the use of high-frequency sound waves.

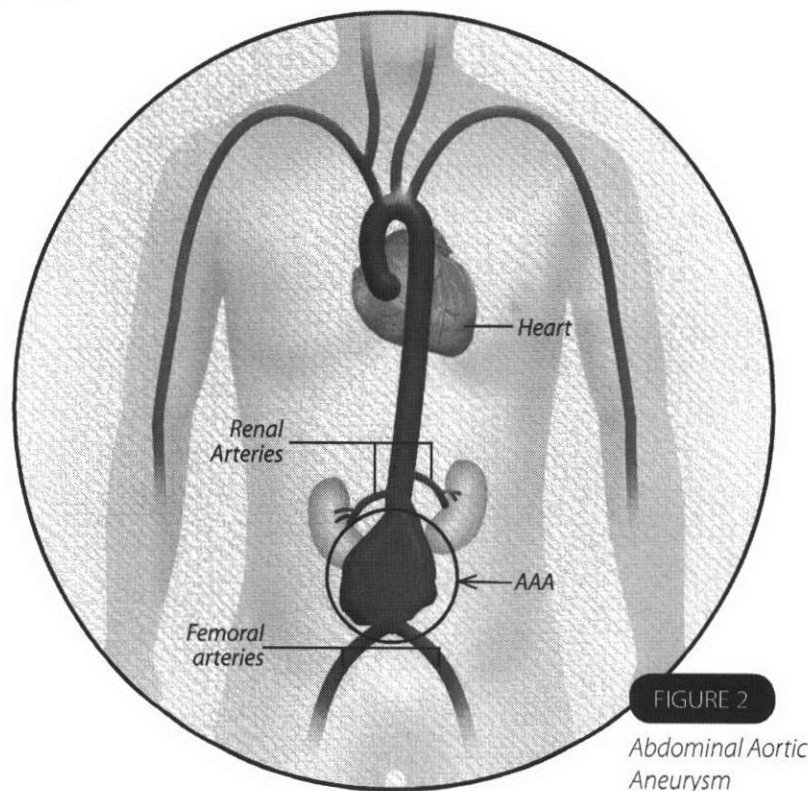
ABDOMINAL AORTA

The **aorta** is the largest blood vessel in the body. It carries blood away from the heart to the rest of the body. The abdominal aorta is the part of the **aorta** located in the abdomen (see **Figure 1**).



ABDOMINAL AORTIC ANEURYSM

An **aneurysm** is the bulging or ballooning of a weakened area of a blood vessel. The wall of the **aorta** can become weak due to age, disease or trauma. This may cause the aortic wall to bulge, leading to an AAA (see **Figure 2**). As the bulge grows, the wall of the **aorta** becomes weaker. This may cause the **aorta** to rupture and lead to massive internal bleeding. A ruptured **aneurysm** can cause death and needs immediate medical attention.



CAUSES

The risk of developing an **AAA** increases with age. AAA usually affects people over 50 years of age and is more common in men than in women. Other risks include smoking and high blood pressure. A patient with a family history of AAA is at higher risk and should consult a doctor.

SYMPTOMS

In most cases, patients have no symptoms of an **AAA**. However, for those patients with symptoms, the most common one is pain in the abdomen, back or chest. The pain may range from mild to severe. Some patients might feel the aneurysm as a throbbing mass in their abdomen. An AAA is often discovered during an examination being done for other unrelated health reasons. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen. Most often, **aneurysms** are found during a medical test such as a **CT scan** or **ultrasound**.

TREATMENT OPTIONS

If your doctor thinks there is a risk that your **AAA** may rupture, he/she may recommend treatment. There are two primary treatment options available depending on your doctor's diagnosis:

OPEN SURGERY or ENDOVASCULAR STENT GRAFTING

OPEN SURGERY

In this treatment option, the doctor repairs the **aorta** by making a large cut in the abdomen (see **Figure 3**). The **aneurysm** section of the **aorta** is removed and replaced with a fabric graft.

The fabric graft is sewn into place and acts as a replacement blood vessel. The blood flow through the **aorta** is stopped while the graft is put in place.

Open surgery is typically performed under general anesthesia. It takes about three to four hours to complete. Patients typically spend one to two days in an intensive care unit and typically remain in the hospital for one week. Patients may require two to three months to recover completely. Open repair is a proven medical procedure.

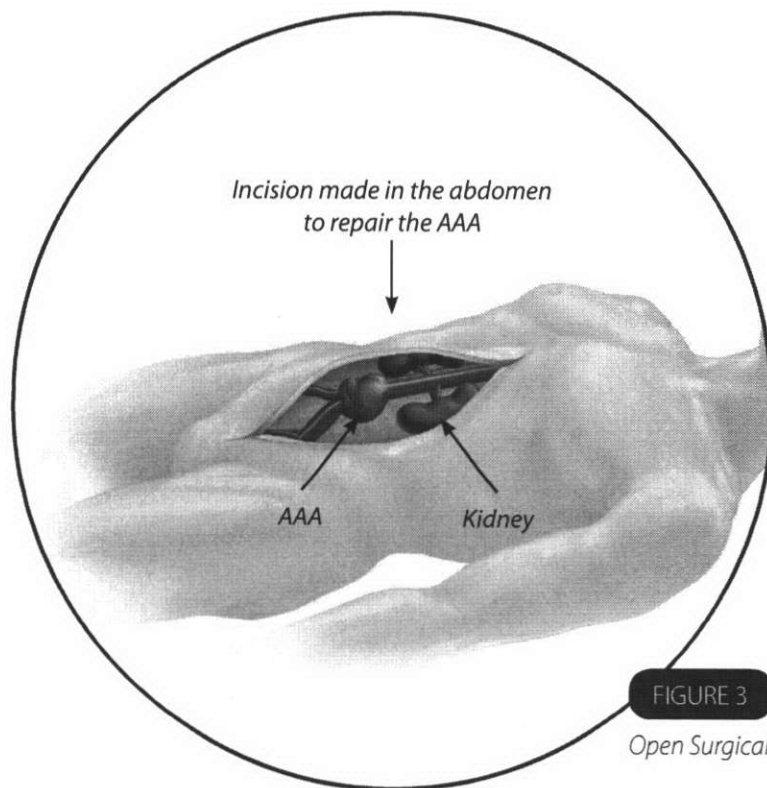


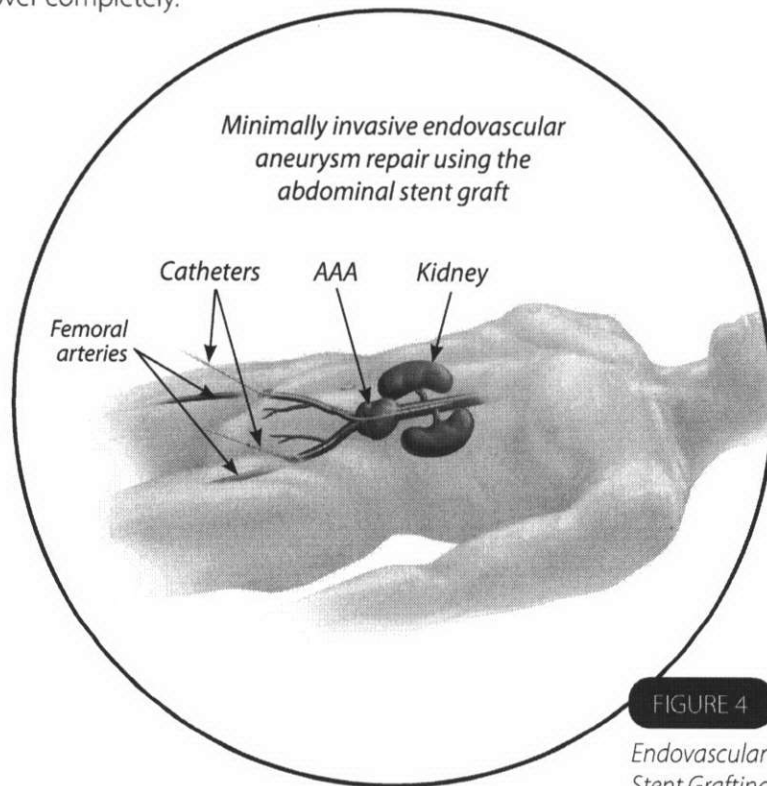
FIGURE 3

Open Surgical Repair

ENDOVASCULAR STENT GRAFTING

This is a **minimally invasive** procedure. A **stent graft** (such as the **abdominal stent graft**) is placed inside the aneurysm without surgically opening the tissue surrounding it (see **Figure 4**). The stent graft is a fabric tube supported by a metal framework.

This procedure is typically performed under local, regional or general anesthesia. It takes about one to three hours to complete. Patients typically spend a few hours in the intensive care unit and typically remain in the hospital for one to two days. Patients may require four to six weeks to recover completely.



Risks and benefits are associated with both treatment options. Patients should talk with their doctors about which option is best for them.

ABDOMINAL STENT GRAFT

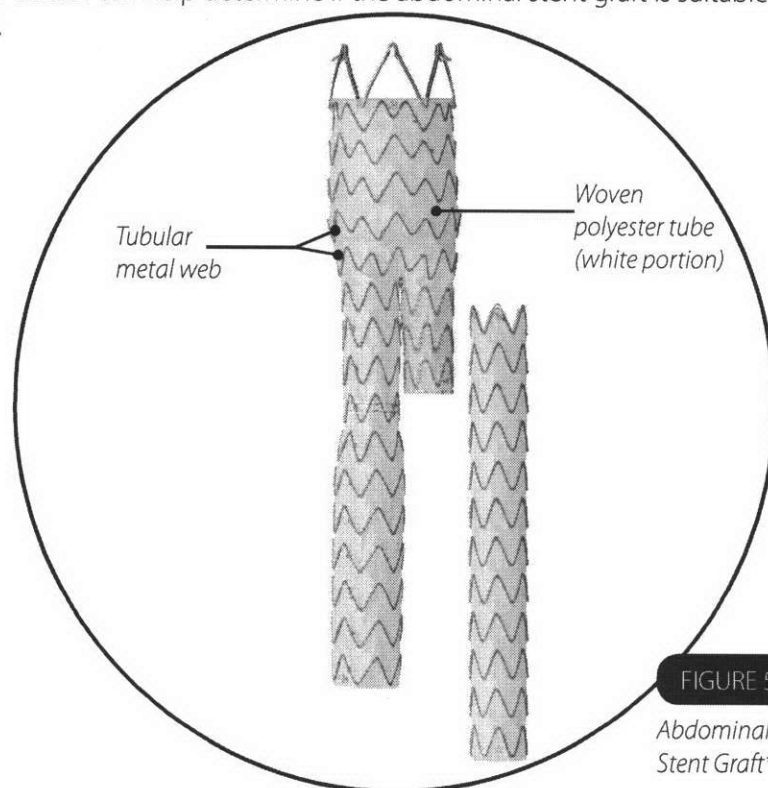
The **abdominal stent graft** is a fabric tube supported by a metal framework (see **Figure 5**). It is placed in the **aorta** using a catheter. The **stent graft** is designed to **exclude** the **aneurysm**. The **stent graft** reduces the pressure on the **aneurysm** and provides a new pathway for blood flow. This reduces the risk of **rupture**.

The abdominal stent grafts manufactured by Medtronic are typically made from nitinol (nickel-titanium), polyester and platinum-iridium.

Do not get the **abdominal stent graft** if:

- You have a condition that can infect the stent graft
- You are allergic to the stent graft materials

Your doctor can help determine if the abdominal stent graft is suitable for you.



*NOTE: The stent graft shown in the figure above is not representative of the actual size. The abdominal stent grafts manufactured by Medtronic typically range in length from 124 mm (4.88 in.) to 185 mm (7.28 in.).

RISKS

As with any endovascular stent graft, the abdominal stent graft comes with risks. Please discuss all risks with your doctor. Major risks associated with abdominal endovascular stent grafts include, but are not limited to:

- Endoleaks— An endoleak is the leaking of blood around the graft into the aneurysm. Endoleaks can be detected using CT scans. Most endoleaks do not require treatment. Your doctor can decide if you need any treatment.
- Stent graft movement— This is the movement of the stent graft from its original position over time. This can be assessed using imaging techniques like CT scans. Your doctor can decide if you need any treatment.
- Device-related issues (for example, breaking sutures or the metal portion of the stent graft) — These issues may be detected using imaging techniques such as X-rays. Your doctor can decide if you need any treatment.
- Aneurysm Rupture
- The use of this device requires fluoroscopy and use of dyes for imaging. Patients with kidney problems may be at risk of kidney failure due to the use of dyes.
- Swelling of the groin area
- Nausea and vomiting
- A hole or a tear of the blood vessels are risks associated with any catheter-based procedure. These risks may increase with the use of large-sized catheters.
- Formation of an abnormal passage between your arteries and veins
- Bowel complications including death of a portion of your bowel tissue requiring surgical removal
- Cramping pain and weakness in the legs and especially the calves
- Formation of blood clots that block the flow of blood to your organs
- Fever and inflammation

- Problems affecting your urinary and reproductive organs including infection and tissue death
- Impotence
- Infection of the aneurysm and device access site
- Complications of the nervous system including total or partial paralysis of the lower half of the body with involvement of both legs, confusion, stroke, and transient ischemic attack
- Blockage of the device or blood vessel
- Kidney problems
- Liver problems
- Additional endovascular procedures
- Surgical conversion to open repair
- Infection, pain or bleeding in wounds
- Death

BENEFITS

There are a number of benefits¹ to having an abdominal stent graft procedure. Some of these are listed below:

- The procedure is minimally invasive.
- The procedure can be performed under local anesthesia.
- There is a lower surgical complication rate.
- The patient may lose less blood during the procedure. This reduces the risk of blood transfusion.
- The patient may spend less time in the intensive care unit after the procedure, and have a short hospital stay.

¹ Based on clinical study data for abdominal stent grafts manufactured by Medtronic. The long-term results of the abdominal stent graft have not yet been established.

ABDOMINAL STENT GRAFT PROCEDURE

Before the procedure:

Prior to the procedure, **imaging** tests like **CT scans** are performed. These tests allow the doctor to assess the **aneurysm**.

During the procedure:

This procedure is performed using anesthesia. A small cut is made on both sides of the groin to prepare for the stent grafting procedure.

Fluoroscopy is used to guide the catheter to the **AAA**. The catheter is a long, thin tube-like device used to place the **stent graft** in the **aorta**. The catheter is advanced through the large vessel in the patient's groin (**femoral artery**) to reach the abdominal **aneurysm** (see **Figure 6**).

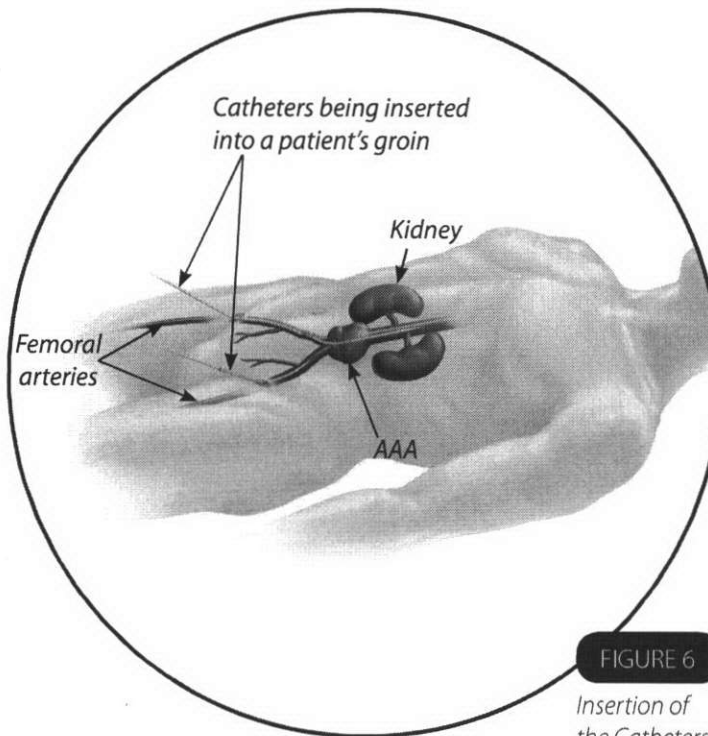


FIGURE 6

Insertion of
the Catheters

The **stent graft** is slowly released from the catheter into the **aorta**. As the stent graft is released, it expands to its proper size so that it snugly fits into the **aorta** both above and below the **aneurysm**. The catheter is then removed from the body. The stent graft remains inside the **aorta** permanently (see **Figure 7**). Additional stent grafts may be required to completely **exclude** the aneurysm. **Imaging** procedures are often performed to check whether the stent graft is properly placed.

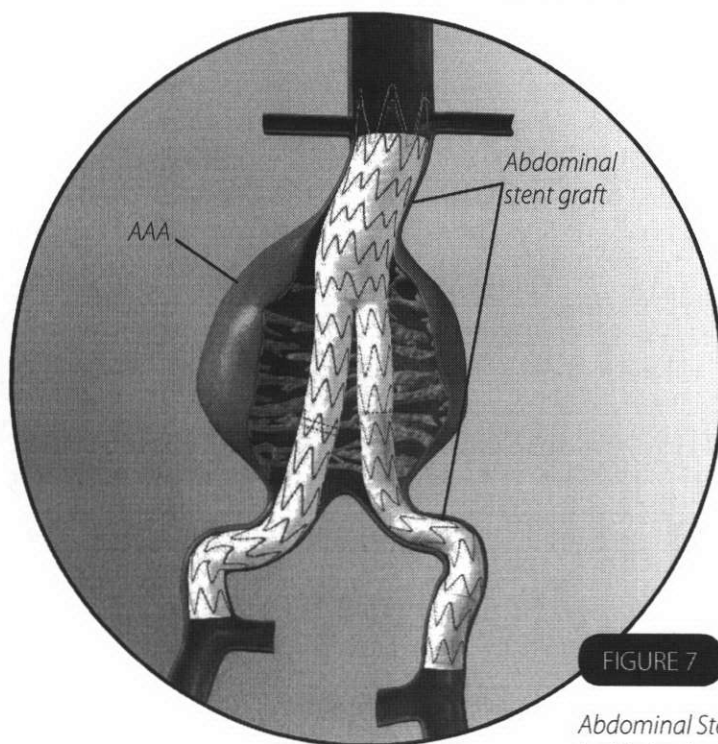


FIGURE 7

*Abdominal Stent Graft
Inside the Aneurysm*

After the procedure:

Immediately after recovery from the stent grafting procedure, you may be required to lay flat for four to six hours. This will allow the leg wounds to start healing. Some mild discomfort may be felt at the wounds in the groin. This usually resolves in two days. Side effects may include swelling of the groin area, numbness of the legs, nausea, vomiting, leg pain or throbbing, lack of appetite, fever and/or absence of bowel movement for one to three days.

WHAT SYMPTOMS SHOULD PROMPT YOU TO CALL YOUR DOCTOR AFTER THE PROCEDURE?

If you experience any of the following symptoms, contact your doctor immediately:

- Pain, numbness, coldness or weakness in the legs or buttocks
- Any back, chest, abdominal or groin pain
- Dizziness, fainting, rapid heartbeat or sudden weakness

A doctor should also be called if you need to reschedule a follow-up visit for any reason.

FOLLOW-UP

It is important to schedule regular follow-up visits with your doctor. Long-term results of this **stent graft** have not yet been established. Most problems with **endovascular** repair do not have symptoms. Thus, follow-up is important to determine the success of your stent graft.

Follow-up visits will help the doctor to check your **aneurysm** and **stent graft** on a regular basis. Some problems that might occur are listed in the Risks section of this booklet. Your doctor will schedule follow-up visits depending on your condition. Most often these will occur at one month, one year and annually thereafter. At each visit, **imaging** such as **CT scans** will be carried out to determine the performance of the **stent graft**. If you have poor kidney function, you should ask your doctor about the dyes used in some of these imaging studies, as they may be harmful.

IMPLANTED DEVICE IDENTIFICATION CARD

After your **abdominal stent graft** procedure, your doctor will give you a temporary implanted device identification (ID) card. The temporary implanted device ID card will tell you the size and number of your abdominal aortic **stent graft** implants.

Medtronic will mail you a permanent implanted device ID card to carry in your wallet. Your permanent ID card will list the following information:

- Type of device implanted

- Date of implant
- Your doctor's information
- **Magnetic Resonance Imaging (MRI)** information

Be sure to tell all of your healthcare providers that you have the stent graft and show them your implanted device ID card. You should keep your patient ID card available at all times.

MAGNETIC RESONANCE IMAGING

After being implanted with the abdominal **stent graft** manufactured by Medtronic, it is still safe to have **MRI** procedures, under certain conditions. MRI information is provided on your implanted device ID card. Show this ID card to your healthcare providers.

LIFESTYLE CHANGES

- You will need to go for regular follow up visits to check your stent graft.
- Please consult your doctor about your ability to perform strenuous physical activities.

The abdominal stent graft is not expected to trigger any passenger screening devices such as airport security scanners. Please consult your doctor to reschedule any follow up visits if you are traveling.

QUESTIONS YOU MAY WANT TO DISCUSS WITH YOUR DOCTOR

- What are the other options for treating **AAA**?
- Which stent grafts are approved for treating **AAA**?
- What are all of the risks associated with an abdominal **stent graft** procedure?
- What are all of the risks associated with open surgical repair?
- Will health insurance pay part or all of the costs associated with this procedure?
- After the procedure, how often must a doctor follow up with the

patient, and which tests will be performed?

- Does a patient have to limit activities after treatment? If so, for how long?
- How long can the **stent graft** remain implanted in the body?
- How many **stent graft** procedures has this facility performed?

This guide is not a substitute for detailed discussions between you and your doctor. Only your doctor can decide if this procedure is suitable for you. This therapy is not for everyone. Please consult your doctor. Prescription is required.

ADDITIONAL INFORMATION

Additional information regarding AAA can be found at:

www.medlineplus.gov

www.fda.gov

CONTACTING MEDTRONIC:

If you have any questions concerning an abdominal stent graft manufactured by Medtronic, you should contact your doctor. It is Medtronic's mission to alleviate pain, restore health and extend life. If there is anything that we as a company can do to assist you, please feel free to contact us at:

Medtronic
3576 Unocal Place
Santa Rosa, CA 95403
USA
Tel: 707.525.0111

CardioVascular LifeLine
Customer Support
Tel: 877.526.7890
Tel: 763.526.7890

NOTES

[illegible]

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There is no text or other markings on the paper.

[illegible]

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

www.medtronic.com

Medtronic Vascular
3576 Unocal Place
Santa Rosa, CA 95403
USA
Tel: 707.525.0111

**CardioVascular LifeLine
Customer Support**
Tel: 877.526.7890
Tel: 763.526.7890

Product Services
Tel: 888.283.7868
Fax: 800.838.3103



Medtronic

For distribution in the USA only.
© 2010 Medtronic, inc. All rights reserved. Printed in USA UC201100108EN 11/10



The Endurant[®] Stent Graft System



Instructions for Use (IFU)

IMPORTANT!

- Do not attempt to use the **Endurant Stent Graft System** before completely reading and understanding the information contained in the Instructions for Use.
- Carefully inspect all product packaging for damage or defects prior to use. Do not use product if any sign of damage or breach of the sterile barrier is observed.
- These devices are supplied **STERILE** for single use only. After use, dispose of the delivery catheters in accordance with hospital, administrative, or government policies. Do not resterilize.
- **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Explanation of symbols on product labeling

Refer to the device labeling to see which symbols apply to this product.



Consult instructions for use at: www.medtronic.com/manuals



Contents: One Device



Do not use if package is damaged



Non-pyrogenic



Peel here



Store at room temperature in a dark, dry place



MR Conditional

Rx only

CAUTION: Federal (USA) law restricts this device for sale by or on order of a physician Manufactured In



Sterilized using irradiation



Catalogue number



Serial number



Use By



Do not reuse



Manufacturer



Manufactured In

Endurant, Reliant, Talent, and Xcelerant are registered trademarks of Medtronic, Inc.

Table of Contents

1. DEVICE DESCRIPTION	1
2. INDICATIONS FOR USE	2
3. CONTRAINDICATIONS	2
4. WARNINGS AND PRECAUTIONS	2
5. ADVERSE EVENTS	6
6. SUMMARY OF CLINICAL STUDY	7
7. PATIENT SELECTION AND TREATMENT	21
8. HOW SUPPLIED	21
9. CLINICAL USE INFORMATION	22
10. IMPLANT INSTRUCTIONS	24
11. BAIL-OUT TECHNIQUES	30
12. FOLLOW-UP IMAGING RECOMMENDATIONS	31
13. ADDITIONAL SURVEILLANCE AND TREATMENT	32
14. DISCLAIMER OF WARRANTY	32
15. DEVICE REGISTRATION	32

1 DEVICE DESCRIPTION

The Endurant® Stent Graft System is designed to treat infrarenal abdominal aortic or aorto-iliac aneurysms using an endovascular approach. When placed within the aneurysm, the Endurant Stent Graft provides a permanent, alternative conduit for blood flow within the patient's vasculature.

The stent graft system is comprised of 2 main components: the implantable Endurant Stent Graft and the disposable Endurant Delivery System. The stent graft is preloaded into the delivery system and advanced to the aneurysm using fluoroscopic guidance. Upon deployment, it self-expands to conform to the shape and size of the seal zones above and below the aneurysm.

1.1 Stent Graft

The Endurant Stent Graft (Figure 1) has 2 main components: an aorto-iliac bifurcated component and a contralateral limb. Additional components include aortic and iliac extensions. After placement of the bifurcated component, the contralateral limb and additional components are introduced separately into the vessel and mated with the implanted component(s).

All stent graft components are composed of nitinol stents sewn to a fabric graft. Radiopaque markers are sewn onto each component of the stent graft to aid in visualization and to facilitate accurate placement. The Nitinol stents are also visible under fluoroscopy.

Stent graft components should be oversized to be larger than the measured vessel inner diameter (aortic components are oversized approximately 10-20%; limb components are oversized approximately 10-25%). Section 9.2 contains detailed sizing information for all stent graft components, including available ranges of length and diameter. Table 1 contains a summary of the stent graft materials.

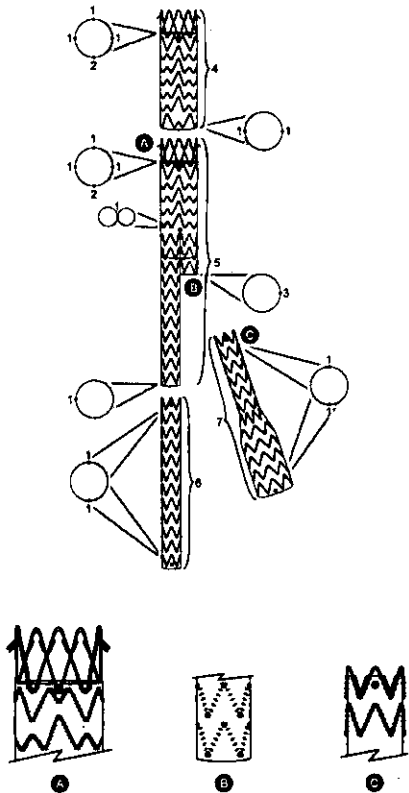


Figure 1: Endurant Stent Graft Components

Note: This and all other product graphics appearing in this manual are not drawn to scale.

1. Radiopaque Marker
2. 'e' Marker
3. Radiopaque Gate Marker
4. Aortic Extension
5. Bifurcated Component
6. Iliac Extension
7. Contralateral Limb

Table 1: Stent Graft Materials

Component	Material
Stents	Nickel-Titanium (Nitinol) Alloy
Button Radiopaque Markers	Platinum-Iridium Alloy
e Radiopaque Marker	Platinum
Contralateral Gate Marker	Gold
Graft Fabric	Polyester
Suture	Polyester and Polyethylene

The Endurant Stent Graft System does not contain natural rubber latex; however, during the manufacturing process, it may have incidental contact with latex.

1.1.1 Bifurcated Component

The proximal section of the bifurcated component deploys into the proximal neck and upper section of the aneurysm. The proximal aortic section of the bifurcated component is composed of Nitinol stents sewn to a fabric graft. The suprarenal portion of the proximal stent is not covered with graft fabric (Figure 1). The suprarenal stent has anchor pins to fix the stent graft in place.

The aortic section distally bifurcates into 2 smaller tubes: an ipsilateral single iliac limb and a short contralateral leg. The ipsilateral limb stents are sewn to the outside of the graft fabric creating a smooth inner lumen. The contralateral leg stents are sewn to the inside of the graft fabric (Figure 1).

1.1.2 Contralateral Limb Component

The proximal end of the contralateral limb component deploys within the short contralateral leg of the bifurcated component, while the distal end of the contralateral limb component deploys into the contralateral iliac artery. The proximal section of the contralateral limb component has an open web configuration (Figure 1), which contains no graft material in its stent valleys.

1.1.3 Iliac Extension Component

If additional distal stent graft length is needed, iliac extension components are available. The iliac extension component has an open web configuration on its proximal end.

1.1.4 Aortic Extension Component

If additional proximal stent graft length is needed, aortic extension components are available. The aortic component has a bare proximal suprarenal stent with anchor pins.

1.2 Delivery System

The Endurant Delivery System, based on the Xcelerant Delivery System consists of a single-use, disposable catheter, with an integrated handle to provide accurate, controlled deployment. The catheter assembly is flexible and compatible with a 0.035 in (0.89 mm) guidewire. There are 2 types of Endurant delivery systems: the Endurant Aortic Delivery System (Figure 2) delivers the bifurcated component and aortic extension. The Endurant Iliac Delivery System (Figure 3) delivers the contralateral limb and iliac extension. The aortic delivery system features a tip capture mechanism, which is not present in the iliac delivery system.

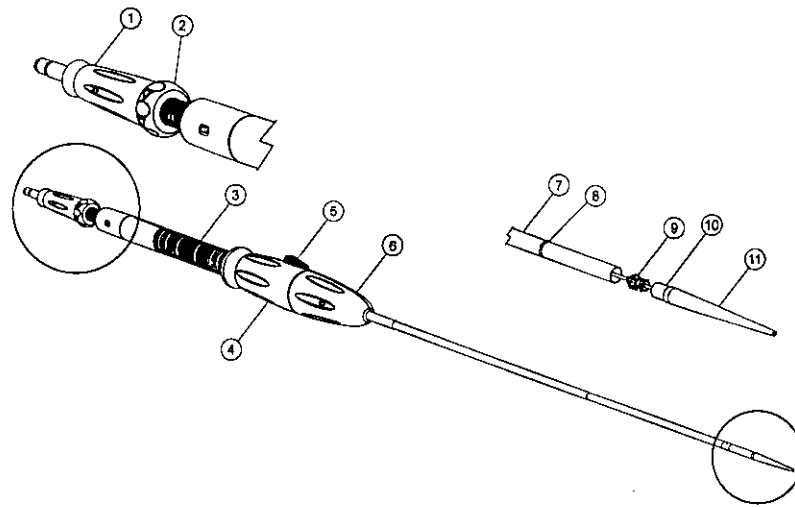


Figure 2: Aortic Delivery System

1. Rear Handle
2. Back-End Wheel
3. Screw Gear
4. External Slider
5. Trigger
6. Front Grip
7. Graft Cover
8. Markerband
9. Spindle
10. Sleeve
11. Tapered Tip

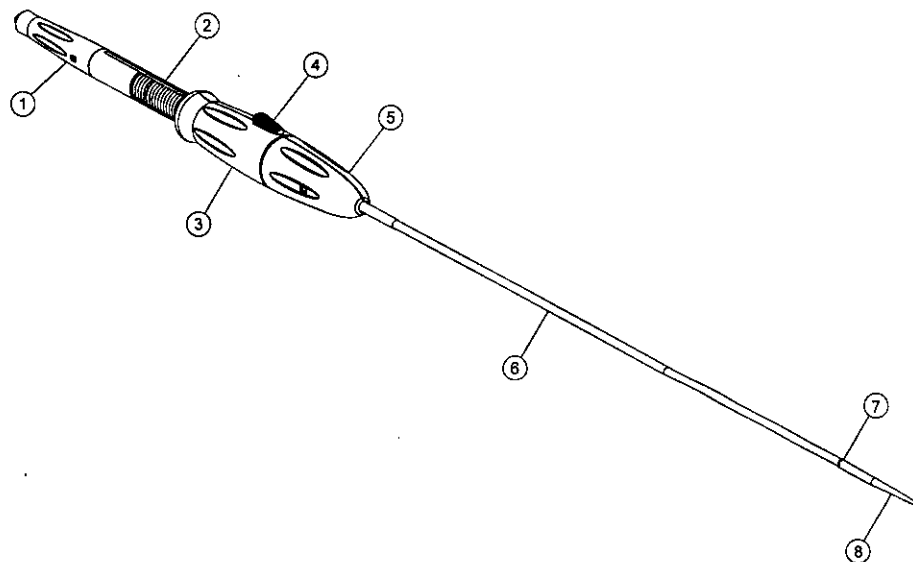


Figure 3: Iliac Delivery System

1. Rear Handle
2. Screw Gear
3. External Slider
4. Trigger
5. Front Grip
6. Graft Cover
7. Markerband
8. Tapered Tip

2 INDICATIONS FOR USE

The Endurant Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms in patients with the following characteristics:

- Adequate iliac or femoral access that is compatible with vascular access techniques, devices, or accessories
- Proximal neck length of ≥ 10 mm
- Infrarenal neck angulation of $\leq 60^\circ$
- Distal fixation length of ≥ 15 mm
- Aortic neck diameters with a range of 19 to 32 mm
- Iliac diameters with a range of 8 to 25 mm
- Morphology suitable for aneurysm repair

3 CONTRAINDICATIONS

The Endurant Stent Graft System is contraindicated in:

- Patients who have a condition that threatens to infect the graft.
- Patients who are sensitive to or have allergies to the device materials listed in Table 1.

Also consider the information in Section 4.2, Patient Selection.

4 WARNINGS AND PRECAUTIONS

Caution: Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

4.1 General

- The Endurant Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of this device. Specific training expectations are described in Section 9.1, Physician Training Requirements.
- Always have a vascular surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

4.2 Patient Selection

- The long-term safety and effectiveness of the Endurant Stent Graft System has not been established.
- Do not use the Endurant Stent Graft System in patients unable to undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedure described in Sections 9 - 12.
- The Endurant Stent Graft System is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The Endurant Stent Graft System is not recommended in patients exceeding weight and/or size limits necessary to meet imaging requirements.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation ($>60^\circ$); short proximal aortic neck (<10 mm); and thrombus and/or calcium formation at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Irregular calcification and/or plaque may compromise the fixation and sealing of the implantation sites. Necks exhibiting these key anatomic elements may be more conducive to graft migration.
- Iliac conduits may be used to ensure the safe insertion of the delivery system if the patient's access vessels, as determined by treating physician, preclude safe insertion of the delivery system.
- Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications.
- The safety and effectiveness of the Endurant Stent Graft System has not been evaluated in patients who:
 - Are less than 18 years of age
 - Are pregnant or lactating
 - Have an aneurysm that is:
 - Suprarenal
 - Juxta-renal/ Para-renal
 - Isolated ilio-femoral
 - Mycotic
 - Inflammatory
 - Pseudoaneurysm
 - Have a dominant patent inferior mesenteric artery and an occluded or stenotic celiac and/or superior mesenteric artery
 - Have an untreated thoracic aneurysm >4.5 cm in diameter
 - Requires emergent aneurysm treatment, e.g., trauma or rupture
 - Have a history of bleeding diathesis or coagulopathy

- Have had a myocardial infarction (MI) or cerebral vascular accident (CVA) within 3 months prior to implantation
- Have a reversed conical neck defined as a >4 mm distal increase over a 10 mm length
- Have a known hypersensitivity or contraindication to anticoagulants, antiplatelets, or contrast media, which is not amenable to pre-treatment
- Have significant (typically >25% of vessel circumference of aortic neck and iliac artery, and/or >50% of the length of the iliac artery) aortic mural thrombus at either the proximal or distal attachment centers that would compromise fixation and seal of the device bilaterally
- Have ectatic iliac arteries requiring bilateral exclusion of hypogastric blood flow
- Have arterial access site that is not expected to accommodate the diameter of the device (14F-20F) due to size or tortuosity
- Have active infection at the time of the index procedure documented by pain, fever, drainage, positive culture and/or leukocytosis (WBC >11,000 mm³) that is treated with antimicrobial agents (nonprophylactic)
- Have congenital degenerative collagen disease, e.g., Marfan's Syndrome
- Have a creatinine >2.0 mg/dl (or >182 µmol/L)
- Are on dialysis
- Have connective tissue disorder
- All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the health and performance of the implanted endovascular stent graft. Patients with specific clinical findings (e.g. endoleaks, enlarging aneurysms or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in Section 12, Follow-up Imaging Recommendations.
- Patients experiencing reduced blood flow through the graft limb and/or leaks may be required to undergo secondary interventions or surgical procedures.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and/or endoleak. An increase in aneurysm size and/or persistent endoleak may lead to aneurysm rupture.

4.3 Before Implant

- Pre-operative planning for access and placement should be performed before opening the device packaging.
- Carefully inspect the Endurant Stent Graft System packaging and system for damage or defects prior to use. Do not use product if any sign of damage or breach of the sterile barrier is observed. Do not attempt to resterilize the Endurant Delivery System or the Endurant Stent Graft Components.
- Do not bend, kink, or otherwise alter the Endurant Delivery System prior to implantation because it may cause deployment difficulties.
- To reduce the risk of thrombotic problems, an additional bolus of IV heparin should be administered before inserting the device.

4.4 During Implant

- Exercise care in handling and delivery technique to help prevent vessel rupture.
- Studies indicate that the danger of micro-embolization increases with increased procedure duration.
- Renal complications may occur:
 - from an excess use of contrast agents
 - as a result of embolic or misplaced stent graft
- Do not deploy the stent graft components in a location that could cause an endoleak or occlude arteries necessary to supply bloodflow to organs or extremities. This could necessitate surgical removal of the device.
- Use fluoroscopic guidance to advance the delivery system and to detect kinking or alignment problems with the stent graft components. Do not use excessive force to advance or withdraw the delivery system when resistance is encountered. If the delivery system kinks during insertion, do not attempt to deploy the stent graft component. Remove the device and insert a new delivery system.
- Do not continue to torque the delivery system without tip response.
- Exercise particular care in difficult areas, such as areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system.
- Inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent graft.
- Systemic anticoagulation should be used during the implantation procedure based on hospital or physician protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
- Stent graft components cannot be replaced or drawn back into the delivery system, even if the stent graft component is only partially deployed.
- If the graft cover is accidentally withdrawn, the device will prematurely deploy and may be incorrectly positioned.
- When deploying the stent graft, be sure to hold the front grip of the delivery system stationary.
- If a balloon catheter is used, do not over-inflate or inflate outside the graft material. Follow all manufacturer instructions regarding catheter operation.
- High pressure injections of contrast media made at the edges of the stent graft immediately after implantation may cause endoleak.

4.5 Treatment and Follow-up

- Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.
- Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:
 - Aneurysm growth >5 mm (with or without endoleak) since last follow-up.
 - Change in aneurysm pulsatility (with or without growth or endoleak).
 - Persistent endoleak (with or without aneurysm growth).
 - Stent graft migration resulting in an inadequate seal zone.
 - Decrease in renal function due to renal artery occlusion (migration or poor placement).
- All patients with endovascular aneurysm repair should undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.
- Non-clinical testing has demonstrated that the Endurant Stent Graft System is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems only using the specific testing parameters listed in Section 9.6, MRI Information.

5 ADVERSE EVENTS

5.1 Observed Adverse Events

Major adverse events observed in the clinical study supporting approval of the device are provided in Section 6.5.1, Tables 10 through 13.

5.2 Potential Adverse Events

Adverse events that may occur or require intervention include, but are not limited to:

- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Arterial or venous thrombosis or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the aneurysm, device access site, including abscess formation, transient fever and pain
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis)
- Occlusion of device or native vessel
- Pulmonary complications and subsequent attendant problems
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Stent graft: improper component placement; incomplete component deployment; component migration; suture break; occlusion; infection; stent fracture; graft twisting or kinking; insertion and removal difficulties; graft material wear; dilatation; erosion; puncture and perigraft flow
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection.
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)
- Vessel damage
- Wound complications and subsequent attendant problems (eg, dehiscence, infection, hematoma, seroma, cellulitis)

5.3 Device-Related Adverse Events Reporting

Any adverse event or clinical incident involving the Endurant Stent Graft System should be immediately reported to Medtronic Vascular. To report an incident in the US, call (800) 465-5533.

6 SUMMARY OF CLINICAL STUDY

The objective of the Endurant Stent Graft System US Clinical Study was to evaluate the safety and effectiveness of the Endurant Stent Graft System in the treatment of infrarenal abdominal aortic and aorto-iliac aneurysms. The study was a controlled, prospective, non-randomized, multi-center trial. 150 subjects were enrolled across 26 United States' sites. The Endurant Test Group was compared to subject data from the Talent IDE study.

The analysis included endpoints that are consistent with current literature and other endovascular aneurysm repair (EVAR) clinical studies. The primary safety endpoint for this analysis was the proportion of patients free from a MAE within 30 days of the index procedure (based on a composite MAE rate), compared to the Talent Control Group. The primary effectiveness endpoint for this analysis was successful aneurysm treatment at 1 year. Successful aneurysm treatment was an endpoint that included successful delivery and deployment, aneurysm growth, endoleaks, stent graft occlusion, conversion to surgery, rupture and migration. Secondary study endpoints and analyses were also presented. Follow up evaluations were conducted at 1 month, 6 months, 12 months, and will be conducted annually thereafter for a total of 5 years from the index procedure.

6.1 Subject Accountability and Follow-up

For the Endurant Test Group, all 150 enrolled subjects were eligible for clinical and imaging follow-up at 1-month. Of the 150 subjects, 99% (149/150) had a both a clinical follow-up and imaging follow-up. Through the first 12 months, 6 subjects died and none withdrew or was lost to follow-up. At the 12-month follow-up interval, 132 subjects were eligible for clinical and imaging follow-up and 12 subjects were pending for the 12-month visit. Of the 132 subjects, 97% (128/132) had a clinical follow-up and 98% (129/132) had an imaging follow-up.

Detailed subject accountability and follow-up are presented in Table 2.

Table 2: Subject and Imaging Accountability – Endurant Test Group¹

Interval (Analysis Window)	Subject follow-up			Subjects with imaging performed (Core Lab)		Subjects with adequate imaging to assess the parameter (Core Lab)				Subject events occurring before next visit					
	Eligible	Clinical Follow-up	Imaging Follow-up	CT/MRA Imaging	KUB Imaging	Aneurysm size increase	Endoleak	Migration	Technical Observation ²	No Implant	Conversion to Surgery	Death	Withdrawal	Lost to Follow-up	Not Due for Next Visit
Originally Enrolled	150									0					
Events after implant but before a 1 Month visit											0	0	0	0	0
1 Month (Day 1-90)	150	149 (99%)	149 (99%)	147 (98%)	124 (83%)		143 (95%)		149 (99%)						
Events after 1 Month visit but before a 6 Month visit											0	2	0	0	0
6 Month (Day 91-304)	148	143 (97%)	138 (93%)	135 (91%)	134 (91%)	132 (89%)	129 (87%)	132 (89%)	138 (93%)						
Events after 6 Month visit but before a 12 Month visit											0	4	0	0	12
12 Month (≥ Day 305 ³)	132	128 (97%)	129 (98%)	128 (97%)	125 (95%)	127 (96%)	123 (93%)	125 (95%)	129 (98%)						

¹ Data analysis sample size varies for each of the timepoints above and in the following tables. This variability is due to subject availability for follow-up, as well as, quantity and quality of images available from specific timepoints for evaluation. For example, the number and quality of images available for evaluation of endoleak at 6 months is different than the number and quality of images available at 12 months due to variation in the number of image exams performed, the number of images provided from the clinical site to the Core Lab, or the number of images with acceptable evaluation quality.

² Technical observations assessed by imaging include stent-graft kinking, stent-graft twisting, stent-graft wireform fracture, suprarenal bare stent fracture, anchor pin fracture, and stent-graft stenosis.

³ In cases where 12 month imaging follow-up data were not available, subsequent imaging follow-up data were used.

6.2 Study Demographics and Baseline Medical History

The demographics between the Endurant Test Group and Talent Control Group were comparable. The mean age and sex/gender distribution were similar between the 2 study groups. In addition, the baseline medical history were also similar with high prevalence of hypertension, chronic obstructive pulmonary disease and tobacco use in the past 10 years in both study groups. The baseline SVS/AAVS risk classifications were also similar with over 80% subjects with SVS 2 or above in both study groups.

Table 3 through Table 5 provides the demographics, baseline medical history and SVS risk classification of the Endurant Test Group and the Talent Control Group.

Table 3: Subject Demographics

Parameter	Statistics/Category	Endurant Test Group (N=150)	Talent Control Group (N=166)	p-value ¹
Age (years)				
	Mean \pm SD	73.1 \pm 8.0	74.1 \pm 7.5	0.255
	Median	73.0	76.0	
	Min, max	52, 88	51, 89	
Sex/Gender % (m/n)				
	Male	91.3% (137/150)	91.6% (152/166)	>0.999
Race % (m/n)				
	White	98.7% (148/150)	92.8% (154/166)	0.013
	Non-white	1.3% (2/150)	7.2% (12/166)	
¹ p-values were based on t-tests for continuous variables and Fisher's Exact test for categorical variables.				

Table 4: Baseline Medical History

Body System / Condition	Endurant Test Group % (m/n)	Talent Control Group % (m/n)	p-value ¹
Cardiovascular			
Angina	18.0% (27/150)	16.9% (28/166)	0.882
Arrhythmia	39.3% (59/150)	44.0% (73/166)	0.426
Congestive heart failure	16.0% (24/150)	28.3% (47/166)	0.010
Hypertension	86.7% (130/150)	83.7% (139/166)	0.528
Myocardial infarction	30.0% (45/150)	38.6% (64/166)	0.124
Peripheral vascular disease	22.7% (34/150)	46.4% (77/166)	<0.001
Renal			
Renal insufficiency	28.7% (43/150)	33.1% (55/166)	0.397
Other abnormal body systems			
Chronic obstructive pulmonary disease	35.3% (53/150)	39.2% (65/166)	0.488
Diabetes	26.7% (40/150)	15.7% (26/166)	0.019
Tobacco use in the last 10 years	44.0% (66/150)	44.6% (74/166)	>0.999
¹ p-values were based on Fisher's Exact test.			

Table 5: Baseline Modified SVS Classification

SVS/AAVS Classification	Endurant Test Group % (m/n)	Talent Control Group % (m/n)	p-value ¹
SVS 0	0.0% (0/150)	0.6% (1/166)	0.802
SVS 1	16.0% (24/150)	15.7% (26/166)	
SVS 2	54.7% (82/150)	55.4% (92/166)	
SVS 3	29.3% (44/150)	28.3% (47/166)	
¹ p-value was based on the Cochran-Mantel-Haenzel test for mean score differences in SVS classification			

6.3 Baseline Aneurysm Characteristics

Table 6 and Table 7 provide the baseline aneurysm and anatomical measurements of the Endurant Test Group and Talent Control Group.

Table 6: Baseline Aneurysm Characteristics (Corelab Reported)

Dimension	Statistics	Endurant Test Group	Talent Control Group	p-value ²
Maximum aneurysm diameter (mm)	n ¹	150	156	.
	Mean ± SD	55.9 ± 8.7	55.0 ± 9.3	0.359
	Median	54	53	
	Min, Max	39, 103	38, 88	
Proximal neck diameter (mm)	n ¹	150	156	
	Mean ± SD	23.5 ± 3.0	25.3 ± 3.6	<0.001
	Median	23	26	
	Min, Max	17, 31	16, 32	
Right iliac diameter (mm)	n ¹	148	148	
	Mean ± SD	14.2 ± 4.2	14.5 ± 3.6	0.447
	Median	14	14	
	Min, Max	9, 48	7, 39	
Left iliac diameter (mm)	n ¹	150	153	
	Mean ± SD	13.9 ± 3.1	14.3 ± 3.8	0.347
	Median	14	14	
	Min, Max	8, 24	8, 38	
Proximal neck length (mm)	n ¹	150	154	
	Mean ± SD	31.0 ± 14.3	22.9 ± 12.5	<0.001
	Median	29	21	

Dimension	Statistics	Endurant Test Group	Talent Control Group	p-value ²
	Min, Max	5 ³ , 74	3, 75	
Infrarenal neck angle (°)	n ¹	150	127	
	Mean ± SD	35.2 ± 13.7	30.5 ± 15.8	0.009
	Median	34	30	
	Min, Max	5, 73	0, 72	
Suprarenal neck angle (°)	n ¹	150	NA	
	Mean ± SD	16.0 ± 10.3	NA	NA
	Median	14	NA	
	Min, Max	2, 58	NA	
¹ Number of subjects with readable scans. ² p-values were based on a two-sample t-test ³ Based on Core Lab measurements, two (2) subjects had proximal neck length measurements <10 mm and were outside the margin of error; however, the site reported measurements were > 10 mm.				

Table 7: Distribution of Aneurysm Diameters (Corelab reported)

	Statistics/ Category	Endurant Test Group	Talent Control Group
Maximum Aneurysm Diameter %(m/n) ¹	< 30 mm	0.0% (0/150)	0.0% (0/156)
	30 mm - < 40 mm	0.7% (1/150)	1.3% (2/156)
	40 mm - < 50 mm	16.0% (24/150)	26.3% (41/156)
	50 mm - < 60 mm	63.3% (95/150)	44.2% (69/156)
	60 mm - < 70 mm	13.3% (20/150)	20.5% (32/156)
	70 mm - < 80 mm	4.0% (6/150)	5.8% (9/156)
	80 mm - < 90 mm	1.3% (2/150)	1.9% (3/156)
	90 mm - < 100 mm	0.7% (1/150)	0.0% (0/156)
	100 mm - < 110 mm	0.7% (1/150)	0.0% (0/156)
	≥ 110 mm	0.0% (0/150)	0.0% (0/156)
Aneurysm Diameter %(m/n) < 50 mm		16.7% (25/150)	27.6% (43/156)
Aneurysm Diameter %(m/n) ≥ 50 mm		83.3% (125/150)	72.4% (113/156)
¹ n = number of subjects with readable scans.			

6.4 Devices Implanted

Table 8 provides a breakdown of the number of Endurant Stent Grafts devices implanted at the index procedure per subject.

Table 8: Total Number of Devices Implanted at Initial Procedure

Number of Devices Implanted on a Subject	Endurant Test Group (%m/n) ¹
1	0.7% (1/150)
2	40.0% (60/150)
3	30.0% (45/150)
4	25.3% (38/150)
5	3.3% (5/150)
6	0.7% (1/150)
≥ 7	0.0% (0/150)
¹ Denominator includes all subjects who received the test device.	

Sizes of Devices Implanted

Table 9 below shows the distribution of sizes of the bifurcated stent graft used in the Endurant US Clinical Study.

Table 9: Devices Implanted by Size at Index Procedure

Stent Graft Proximal Diameter (Main Bifurcated, mm)	Endurant % (m/n) ¹
23	10.7% (16/150)
25	26.0% (39/150)
28	36.7% (55/150)
32	22.0% (33/150)
36	4.7% (7/150)
¹ Denominator includes all subjects who received the main bifurcated test device.	

6.5 Study Results: Safety Endpoints

6.5.1 Major Adverse Events (MAEs) Free Rate within 30 Days

Table 10 through Table 11 provide an analysis of the MAEs within 30 days. 96.0% subjects in the Endurant Test Group were MAE-free as compared to 89.2% subjects in the Talent Control Group.

Table 10: MAE free-rate within 30 Days

MAE Free Rate within 30 Days	Endurant Test Group (%m/n)	Talent Control Group (%m/n)
MAEs free-rate within 30 Days	96.0% (144/150)	89.2% (148/166)

Table 11: MAE Components within 30 Days

Major Adverse Event (MAE) within 30 Days¹	Endurant Test Group (%m/n)	Talent Control Group (%m/n)
MAE within 30 days	4.0% (6/150)	10.8% (18/166)
All-cause Death	0.0% (0/150)	1.8% (3/166)
Myocardial Infarction	0.7% (1/150)	1.8% (3/166)
Renal Failure	0.7% (1/150)	1.8% (3/166)
Respiratory Failure	1.3% (2/150)	3.0% (5/166)
Paraplegia	0.0% (0/150)	0.0% (0/166)
Stroke	0.7% (1/150)	1.2% (2/166)
Bowel Ischemia	1.3% (2/150)	0.6% (1/166)
Procedural Blood Loss \geq 1000cc	0.7% (1/150)	5.4% (9/166)
¹ A subject may report multiple MAEs; hence, number of subjects with any MAE may not be the sum of those in each MAE category.		

6.5.2 Major Adverse Events (MAEs) Free Rate within 12 Months

Table 12 through Table 13 provide an analysis of the MAEs within 12 months. 89.2% subjects in the Endurant Test Group were MAE-free as compared to 80.4% subjects in the Talent Control Group.

Table 12: MAE free-rate within 12 Months

MAEs free rate within 12 months	Endurant Test Group (%m/n)¹	Talent Control Group (%m/n)¹
MAEs free-rate within 12 months	89.2% (124/139)	80.4% (123/153)
¹ Denominator includes all subjects who had MAE(s) within 365 days or those were followed for at least 305 days.		

Table 13: Major Adverse Events through 12 Months

MAEs within 12 months¹	Endurant Test Group (%m/n)²	Talent Control Group (%m/n)²
MAE within 12 months	10.8% (15/139)	19.6% (30/153)
All-cause Death	4.3% (6/139)	6.5% (10/153)
Myocardial Infarction	1.4% (2/139)	3.9% (6/153)
Renal Failure	2.2% (3/139)	3.3% (5/153)
Respiratory Failure	2.2% (3/139)	3.9% (6/153)
Paraplegia	0.0% (0/139)	0.0% (0/153)
Stroke	2.9% (4/139)	2.6% (4/153)
Bowel Ischemia	1.4% (2/139)	0.7% (1/153)
Procedural Blood Loss ≥ 1000cc	0.7% (1/139)	5.9% (9/153)
¹ A subject may report multiple MAEs; hence, number of subjects with any MAE may not be the sum of those in each MAE category.		
² Denominator includes all subjects who had MAE(s) within 365 days or were followed for at least 305 days.		

In addition a Kaplan-Meier analysis of freedom from MAEs was performed and is plotted below in Figure 4. Kaplan-Meier analysis predicts a freedom from MAE rate within 12 months of 89.3% in the Endurant Test Group as compared to 81.3% in the Talent Control Group. The data used in the Kaplan-Meier analysis is presented below.

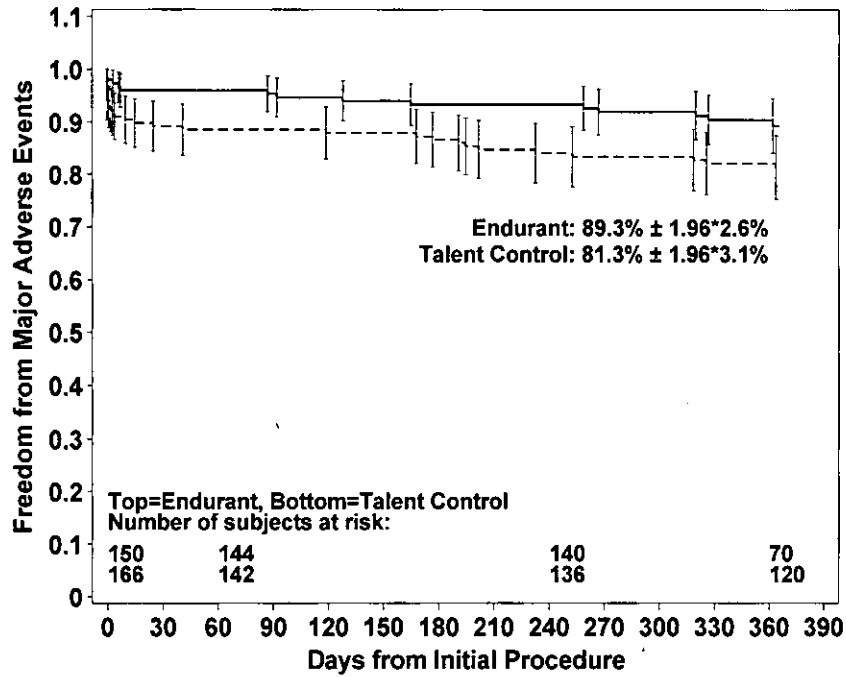


Figure 4: Kaplan-Meier Analysis: Freedom from MAEs through 12 Months

Table 14: Kaplan-Meier Estimates of Freedom from MAEs through 12 Months

	Endurant Test Group			Talent Control Group		
	Treatment to 30 days	31 to 182 days	183 to 365 days	Treatment to 30 days	31 to 182 days	183 to 365 days
No. at Risk ¹	150	144	140	166	142	136
No. of Events	6	4	5	18	4	8
No. Censored ²	0	0	65	6	2	8
Kaplan-Meier Estimate ³	0.960	0.933	0.893	0.891	0.866	0.813
Standard Error	0.016	0.020	0.026	0.024	0.027	0.031

¹ Number of subjects at risk at the beginning of interval.
² Subjects are censored because their last follow-up has not reached the end of the time interval or because they are lost to follow-up.
³ Estimate made at end of time interval.

6.5.3 Aneurysm-related Mortality (ARM) Free-Rate within 12 Months

The ARM free rate within 12 months was 100% in the Endurant Test Group compared to 97.9% in the Talent Control Group as shown in Table 15.

Table 15: Aneurysm-related Mortality Free-Rate within 12 Months

Aneurysm-Related Mortality Free Rate	Endurant Test Group % (m/n) ¹	Talent Control Group % (m/n) ¹
Aneurysm-Related Mortality Free Rate within 12 Months	100.0% (133/133)	97.9% (143/146)
¹ Denominators included all subjects who had the event within 365 days or those were followed for at least 305 days.		

In addition a Kaplan-Meier analysis of freedom from ARM was performed and is plotted below in Figure 5. Kaplan-Meier analysis predicts a freedom from ARM rate within 12 months of 100% in the Endurant Test Group as compared to 98.2% in the Talent Control Group. The data used in the Kaplan-Meier analysis is presented below.

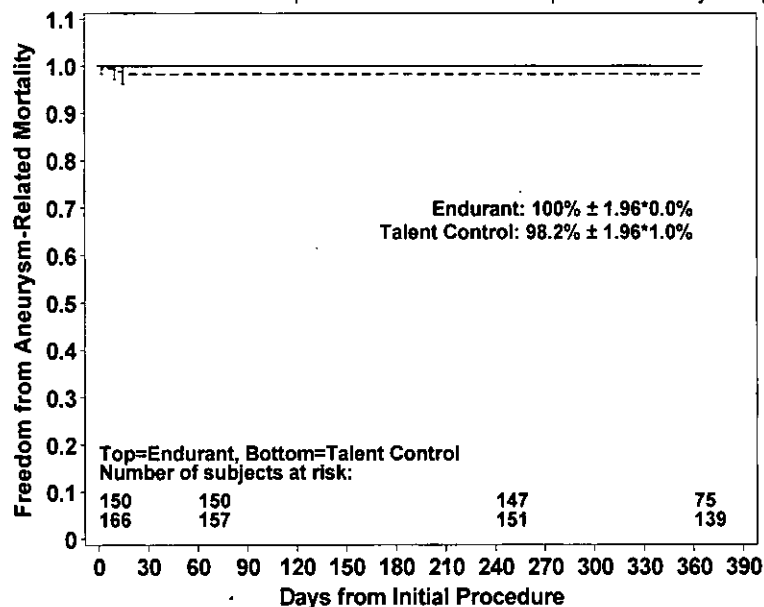


Figure 5: Kaplan-Meier Analysis: Freedom from Aneurysm-Related Mortality within 12 Months

Table 16: Kaplan-Meier Estimates of Freedom from Aneurysm-Related Mortality through 12 months

	Endurant Test Group			Talent Control Group		
	Treatment to 30 days	31 to 182 days	183 to 365 days	Treatment to 30 days	31 to 182 days	183 to 365 days
No. at Risk ¹	150	150	147	166	157	151
No. of Events	0	0	0	3	0	0
No. Censored ²	0	3	72	6	6	12
Kaplan-Meier Estimate ³	1.000	1.000	1.000	0.982	0.982	0.982
Standard Error	0.000	0.000	0.000	0.010	0.010	0.010

¹ Number of subjects at risk at the beginning of interval.

² Subjects are censored because their last follow-up has not reached the end of the time interval or because they are lost to follow-up.

³ Estimate made at end of time interval.

6.5.4 All-cause Mortality Free Rate within 30 Days

Table 17 provides the all-cause mortality free rate within 30 days for the Endurant Test Group and Talent Control Group.

Table 17: All-cause Mortality Free Rate within 30 Days

All-Cause Mortality Free Rate	Endurant Test Group (%m/n)	Talent Control Group (%m/n)
All-Cause Mortality Free Rate within 30 Days	100.0% (150/150)	98.2% (163/166)

6.5.5 All-cause Mortality Free Rate within 12 Months

Table 18 provides the all-cause mortality free rate within 12 months for the Endurant Test Group and Talent Control Group.

Table 18: All-Cause Mortality Free Rate within 12 Months

All-cause Mortality Free Rate	Endurant Test Group (%m/n)	Talent Control Group (%m/n)
All-cause Mortality Free Rate within 12 Months	95.7% (132/138)	93.4% (141/151)
¹ Denominators included all subjects who had the event within 365 days or those were followed for at least 305 days.		

In addition, a Kaplan-Meier analysis of freedom from All-cause Mortality was performed and plotted below in Figure 6. Kaplan-Meier analysis predicts a freedom from all-cause mortality within 12 months of 95.8% in the Endurant Test Group as compared to 93.7% in the Talent Control Group. The data used in the Kaplan-Meier analysis is presented below.

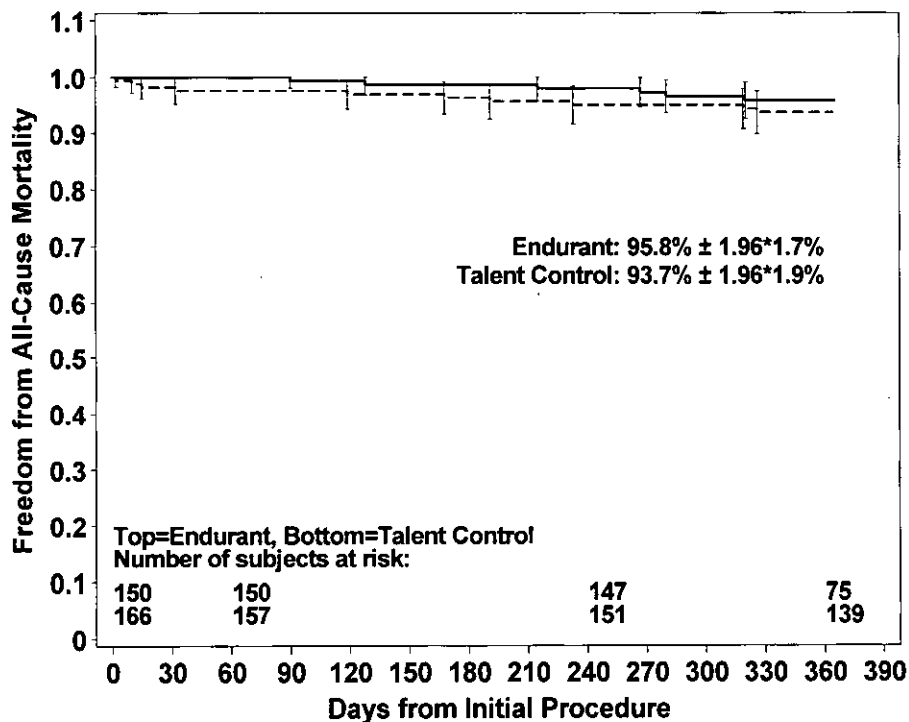


Figure 6: Kaplan-Meier Analysis: Freedom from All-cause Mortality within 12 Months

Table 19: Kaplan-Meier Estimates of Freedom from All-Cause Mortality through 12 Months

	Endurant Test Group			Talent Control Group		
	Treatment to 30 days	31 to 182 days	183 to 365 days	Treatment to 30 days	31 to 182 days	183 to 365 days
No. at Risk ¹	150	150	147	166	157	151
No. of Events	0	2	4	3	3	4
No. Censored ²	0	1	68	6	3	8
Kaplan-Meier Estimate ³	1.000	0.987	0.958	0.982	0.963	0.937
Standard Error	0.000	0.009	0.017	0.010	0.015	0.019
¹ Number of subjects at risk at the beginning of interval. ² Subjects are censored because their last follow-up has not reached the end of the time interval or because they are lost to follow-up. ³ Estimate made at end of time interval.						

6.6 Study Results: Effectiveness Endpoints

6.6.1 Technical Success

During the index procedure, 99.3% subjects in the Endurant Test Group were recorded as having successful delivery and deployment of the Endurant Bifurcated Stent Graft compared to 97.6% of the Talent Control Group. One subject in the Endurant Test Group had the main bifurcated body implanted but the physician was not able to cannulate the contralateral gate due to a pre-existing challenging anatomy. The subject was ultimately converted to aorto-uni-iliac *in-situ* and a femoral to femoral bypass was performed.

Table 20: Technical success

	Endurant Test Group	Talent Control Group
Technical Success ¹	99.3% (149/150)	97.6% (162/166)
¹ Defined as the successful delivery and deployment of the stent graft.		

6.6.2 Successful Aneurysm Treatment

The overall successful aneurysm treatment rate through 12 months in the Endurant Test was 97.5% as compared to 87.1% in the Talent Control Group as shown in Table 21.

Successful aneurysm treatment was an endpoint that included delivery and deployment of the graft and surrogate markers that represented treatment success. This included aneurysm growth, endoleak, occlusion, conversion to surgery, rupture and migration. The information on these endpoints is presented in the sections below.

There were three subjects in the Endurant Test Group that were considered treatment failures. In addition to the technical failure noted above, one subject experienced an aneurysm rupture at the index procedure and the other had a stent graft occlusion necessitating a femoral to femoral bypass.

Table 21: Successful Aneurysm Treatment

	Endurant Test Group % (m/n) ¹	Talent Control Group % (m/n) ¹
Successful Aneurysm Treatment	97.5% (118/121)	87.1% (108/124)
¹ Denominator is number of subjects evaluable for this endpoint		

6.6.3 Change in Aneurysm Diameter

Table 22 provides the change in aneurysm diameter as identified by Core Lab from 1 month to 12 months. In the Endurant Test Group, there were no aneurysm diameter increase >5 mm whereas the Talent Control Group reported that 2.3% of subjects had an aneurysm growth > 5 mm. About 50% subjects had decrease of aneurysm size greater than 5 mm.

Table 22: Aneurysm Diameter Change from 1 Month to 12 Months (Core Lab)

Change in Maximum Aneurysm Diameter from 1 Month to 12 Months ¹	Endurant Test Group % (m/n) ²	Talent Control Group % (m/n) ²
Increase more than 5 mm	0.0% (0/127)	2.3% (3/128)
Stable ³	50.4% (64/127)	64.8% (83/128)
Decrease more than 5 mm	49.6% (63/127)	32.8% (42/128)
¹ Change in aneurysm diameter is based on 1-month imaging. When 1-month imaging was not available, the pre-discharge imaging was used as the baseline.		
² Denominator is number of subjects evaluable for this endpoint.		
³ Stable refers to no change (increase or decrease) of more than 5 mm.		

6.6.4 Endoleak by Visit

Table 23 shows all types of endoleak as identified by Core Lab at 1 month, 6 months and 12 months for Endurant and Talent. There were no Type I and/or III endoleaks at 1 month, 6 months and 12 months in the Endurant group.

Table 23: All Endoleaks at 1-Month, 6-Months and 12-Months (Core Lab)

Endoleaks	1 Month		6 Months		12 Months	
	Endurant Test Group % (m/n ¹)	Talent Control Group % (m/n ¹)	Endurant Test Group % (m/n ¹)	Talent Control Group % (m/n ¹)	Endurant Test Group % (m/n ¹)	Talent Control Group % (m/n ¹)
Type I	0.0% (0/143)	9.3% (14/151)	0.0% (0/129)	4.2% (5/118)	0.0% (0/123)	2.5% (3/122)
Type II	16.1% (23/143)	8.6% (13/151)	11.6% (15/129)	8.5% (10/118)	8.9% (11/123)	6.6% (8/122)
Type III	0.0% (0/143)	0.0% (0/151)	0.0% (0/129)	0.0% (0/118)	0.0% (0/123)	0.0% (0/122)
Type IV	0.0% (0/143)	0.0% (0/151)	0.0% (0/129)	0.0% (0/118)	0.0% (0/123)	0.0% (0/122)
Indeterminate	0.0% (0/143)	1.3% (2/151)	0.0% (0/129)	1.7% (2/118)	0.8% (1/123)	0.8% (1/122)
Subjects had endoleaks of any type ²	16.1% (23/143)	19.2% (29/151)	11.6% (15/129)	14.4% (17/118)	9.8% (12/123)	9.8% (12/122)
¹ Denominator is the number of subjects who had readable images at the time of assessment.						
² A subject may have more than 1 type of endoleaks; hence, number of subjects with any type may not be the sum of those in each type.						

6.6.5 Stent Graft Migration (Corelab)

There was no stent graft migration in the Endurant Test Group through 12 months. There was one case of stent graft migration reported in the Talent Control Group.

Table 24: Stent Graft Migration through 12 Months

	Endurant Test Group % (m/n)²	Talent Control Group % (m/n)²
Stent graft migration through 12 months ¹	0.0% (0/125)	0.8% (1/128)
¹ Migration is defined as evidence of movement of the stent graft relative to fixed anatomic landmarks, which is not due to remodeling of the subject's vasculature. Migration is observed when the stent graft covers a renal artery or movement is >10 mm		

6.6.6 Aneurysm Rupture and Conversion to Surgery

As shown in Table 25, in the Endurant Test Group, one subject experienced an intra-operative aneurysm rupture through 12 months. The rupture occurred during the balloon dilatation (done to ensure good aortic wall apposition and after the implantation of the stent graft during the procedure. The subject was successfully treated endovascularly with an aortic cuff. As of the 12-month period, the subject was alive per site contact. There were no aneurysm ruptures in the Talent Control Group.

There were no conversion to open surgery through 12 months in the Endurant Test Group or the Talent Control Group.

Table 25: Aneurysm Rupture and Conversion to Surgery through 12 Months

	Endurant Test Group % (m/n)¹	Talent Control Group % (m/n)¹
Aneurysm Rupture	0.8% (1/133)	0.0% (0/143)
Conversion to Surgery	0.0% (0/133)	0.0% (0/143)
¹ Denominator is number of subjects evaluable for this endpoint. A subject is evaluable if it had an event within 365 days post-implant or was followed for at least 305 days.		

6.6.7 Stent Graft Patency

Through 12 months, four subjects in the Endurant Test Group experienced stent graft occlusion and three subjects in the Talent Control Group resulting in the stent graft patency rate of 96.8% and 97.5% respectively. All four subjects in the Endurant Test Group underwent secondary procedures and were all treated successfully with blood flow restored to the lower extremity. Multiple factors contributed to the occlusion of the stent grafts including significant calcification in the common iliac artery, significant oversizing of the limb in a tortuous portion of the iliac artery, compression of the stent graft limb by pre-existing thrombus at the aortic bifurcation, and sharp iliac angulation with pre-existing stenosis.

Additionally, one subject experienced graft limb stenosis and was treated successfully with angioplasty and stenting. However, the patient did not experience stent graft occlusion.

6.6.8 Secondary Procedures

Through 12 months, seven subjects required secondary intervention in the Endurant Test Group. Four subjects experienced limb occlusions and were treated successfully. Two subjects were treated for Type II endoleaks; neither subjects experienced an increase in aneurysm diameter. One subject experienced limb graft stenosis and was treated successfully with angioplasty with stenting. This resulted in an overall secondary procedure rate of 5.1%. Sixteen subjects in the Talent Control Group had secondary procedures through 12 months, resulting in an overall secondary procedure rate of 11.1%.

No subjects required secondary procedures to treat Type I and/or Type III endoleak through 12 months in the Endurant Test Group.

Table 26: Secondary Procedures through 12 Months

	Endurant Test Group % (m/n)¹	Talent Control Group % (m/n)¹
Secondary procedures through 12 months	5.1% (7/136)	11.1% (16/144)
¹ Denominator is number of subjects evaluable for this endpoint. A subject is evaluable if it had an event within 365 days post-implant or was followed for at least 305 days.		

6.6.9 Technical Observations

Technical observation is defined as an observed defect or malfunction of the stent graft which is not related to any adverse events. Based on Core Lab assessment, the technical observation rate at 12 months in both the Endurant Test Group and Talent Control Group was 2.3%.

Table 27: Technical Observations through 12 Months (Core Lab)

	1 Month		6 Months		12 Months	
Technical Observations¹	Endurant Test Group % (m/n²)	Talent Control Group % (m/n²)	Endurant Test Group % (m/n²)	Talent Control Group % (m/n²)	Endurant Test Group % (m/n²)	Talent Control Group % (m/n²)
Anchor pin fracture ²	0.0% (0/149)	NA	0.0% (0/138)	NA	0.0% (0/129)	NA
Stent graft kinking/twisting	0.7% (1/149)	4.4% (7/158)	1.4% (2/138)	0.8% (1/129)	0.8% (1/129)	1.5% (2/132)
Stent graft kinking ³	0.7% (1/149)	NA	1.4% (2/138)	NA	0.8% (1/129)	NA
Stent graft twisting ³	0.0% (0/149)	NA	0.0% (0/138)	NA	0.0% (0/129)	NA
Stent graft stenosis	0.7% (1/149)	0.6% (1/158)	0.0% (0/138)	0.0% (0/129)	1.6% (2/129)	0.0% (0/132)
Stent graft wireform fracture	0.0% (0/149)	0.0% (0/158)	0.0% (0/138)	1.6% (2/129)	0.0% (0/129)	0.8% (1/132)
Suprarenal bare stent fracture ⁴	0.0% (0/149)	NA	0.0% (0/138)	NA	0.0% (0/129)	NA
Any Technical Observations ⁶	1.3% (2/149)	4.4% (7/158)	1.4% (2/138)	2.3% (3/129)	2.3% (3/129)	2.3% (3/132)

¹ All other Technical Observations as listed in the Investigational Plan were captured under the "Other" category in the eCRFs. None of these other Technical Observations were reported through 12 months.

NA = not available for following reasons:

² Anchor pin fracture: Talent does not have anchor pins and is therefore not available for comparison.

³ Stent graft kinking/twisting: Talent clinical study did not record kinking and twisting separately and is therefore not available for comparison.

⁴ Suprarenal bare stent fracture: Talent clinical study did not record this category separately and is therefore not available for comparison.

⁶ A subject may have technical observations in more than 1 category; hence, number of subjects with any technical observations may not be the sum of those in each category. Each subject was only counted once in each category.

6.7 Acute Procedural Data

Table 28 compares the clinical utility measures of the Endurant Test Group to the Talent Control Group. Acute procedural outcomes for the Endurant Test Group and the Talent Control Group with respect to procedure duration, blood loss, blood transfusion, time in the Intensive Care Unit (ICU) and length of stay in the hospital are presented below.

Table 28: Acute Procedural Data

Acute Procedural Data	Statistics	Endurant Test Group	Talent Control Group
Duration of procedure (min)	N	150	166
	Mean \pm SD	101.5 \pm 46.2	167.3 \pm 53.2
	Median	91.0	155.0
	Min, Max	34, 318	85, 417
Subjects receiving general anesthesia	% (m/n)	83.3% (125/150)	40.4% (67/166)
Estimated blood loss (cc)	N	149	165
	Mean \pm SD	184.9 \pm 167.9	335 \pm 282.4
	Median	150.0	250.0
	Min, Max	0, 1450	25, 1750
Subjects requiring blood transfusion	% (m/n)	0.7% (1/150)	18.2% (30/165)
Time in ICU (hours)	N	150	166
	Mean \pm SD	6.2 \pm 19.4	19.3 \pm 73.9
	Median	0.0	0.0
	Min, Max	0, 135	0, 864
Overall hospital stay (days)	N	150	166
	Mean \pm SD	2.1 \pm 2.3	3.6 \pm 6.4
	Median	1.0	2.0
	Min, Max	1, 17	1, 79

7 PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

Each Endurant Stent Graft Component must be ordered in a size appropriate to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. The stent graft component should be oversized to be larger than the vessel inner diameter (aortic components are oversized approximately 10-20%; limb components are oversized approximately 10-25%). Refer to section 9.2, Recommended Device Sizing, for further details. The Endurant Stent Graft components cover aortic diameters ranging from 19 mm to 32 mm and iliac diameters from 8 mm to 25 mm. The recommended overall length of the Endurant Stent Graft, including multiple deployed components, should extend from the lowest renal artery to just above the internal iliac (hypogastric) artery. All lengths and diameters of the stent graft components necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters and lengths) are not certain. Use of this approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

Medtronic may consult with physicians to determine proper stent graft component dimensions based on the physician's assessment of the patient's anatomical measurements. The benefits and risks previously described must be considered for each patient before use of the Endurant Stent Graft System.

Caution: Vessel over-distension and damage, or partial stent graft infolding, may be caused by excessive oversizing of the stent graft in relation to the diameter of the blood vessel. Also, due to the nature of the design and the flexibility of the Endurant Stent Graft System, the overall length of each stent graft component may be shorter when deployed.

7.2 Patient Counseling Information

The physician should review the following risks and benefits when counseling the patient about this endovascular device and procedure:

- age and life expectancy
- risks and benefits related to open surgical repair
- risks and benefits related to endovascular repair
- risks related to noninterventional treatment (medical management)
- risks of aneurysm rupture compared to endovascular repair
- possibility that subsequent endovascular or open surgical repair of the aneurysm may be required
- the long-term safety and effectiveness of the Endurant Stent Graft System has not been established
- long-term, regular follow-up is needed to assess patient's health status and stent graft performance
- patients with specific clinical findings (eg, endoleaks, enlarging aneurysms) should be monitored closely
- symptoms of aneurysm rupture

Medtronic recommends that the physician disclose to the patient, in written form, all risks associated with treatment using the Endurant Stent Graft System. Details regarding risks occurring during and after implantation of the device are provided in Section 5, Adverse Events. Additional counseling information can be found in the Patient Information Booklet.

8 HOW SUPPLIED

8.1 Sterility

Each Endurant Stent Graft Component (bifurcated, contralateral limb, and aortic and iliac extensions) is individually contained within an Endurant Delivery System, which is sterilized using Electron Beam sterilization. The Endurant Stent Graft System is supplied sterile for single use only.

- Do not reuse or attempt to resterilize.
- If the device is damaged or the integrity of the sterilization barrier has been compromised, do not use the product and contact your Medtronic Vascular representative for return information.

8.2 Contents

- One Endurant Stent Graft System
- One Set of Patient Tracking Materials

8.3 Storage

Store the system at room temperature in a dark, dry place.

9 CLINICAL USE INFORMATION

9.1 Physician Training Requirements

All Physicians should complete in-service training prior to using the Endurant Stent Graft System.

Caution: The Endurant Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.

Below are the skill/knowledge requirements for physicians using the Endurant Stent Graft System:

- Natural history of AAA and aorto-iliac aneurysms, and co-morbidities associated with AAA repair
- Radiographic, fluoroscopic, and angiographic image interpretation
- Appropriate use of radiographic contrast material
- Arterial cutdown, arteriotomy, and repair
- Percutaneous access and closure techniques
- Nonselective and selective guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Techniques to minimize radiation exposure
- Device selection and sizing

9.2 Recommended Device Sizing

The Endurant Stent Graft System components are available in the sizes described in Tables 29-32. If you have questions about the product or sizing, refer to contact information in the back of the manual.

Table 29: Sizing Chart - Bifurcated Stent Graft

OD (Fr)	Proximal x Distal Diameter (mm x mm)	Covered Length (mm)	Vessel inner diameter (mm)
20	36x20	145, 166	29-32
	36x16		
	32x20	124, 145, 166	26-28
	32x16		
	28x20		23-25
	28x16		
	28x13		
18	25x16		21-22
	25x13		
	23x16		19-20
	23x13		

Table 30: Sizing chart - Aortic Extension

OD (Fr)	Proximal x Distal Diameter (mm x mm)	Covered Length (mm)	Vessel inner diameter (mm)
20	36x36	49 / 70	29-32
	32x32		26-28
	28x28		23-25
18	25x25		21-22
	23x23		19-20

Table 31: Sizing Chart - Contralateral Limb

OD (Fr)	Proximal x Distal Diameter (mm x mm)	Covered Length (mm)	Vessel inner diameter (mm)
16	16x28	82, 93, 124	23-25
	16x24		19-22
	16x20		15-18
14	16x16		12-14
	16x13		10-11
	16x10		8-9

Table 32: Sizing Chart - Iliac Extension

OD (Fr)	Proximal x Distal Diameter (mm x mm)	Covered Length (mm)	Vessel inner diameter (mm)
18	28x28	82	23-25
16	24x24		19-22
	20x20		15-18
14	13x13		10-11
	10x10		8-9

Caution: Proper sizing of the Endurant Stent Graft is the responsibility of the physician. This stent graft sizing incorporates the recommended device oversizing for anatomical dimensions and was based on *in-vitro* test data.

9.3 Device Inspection

Inspect the device and packaging to verify that damage or defect does not exist. If the "Use by" date has elapsed, the device is damaged, or the sterilization barrier has been compromised, do not use the device and contact a Medtronic Vascular representative for return or replacement.

9.4 Additional Equipment Required

- Additional Endurant Stent Graft Systems (bifurcated, contralateral limb, and iliac and aortic extension components) of various lengths and diameters
- Fluoroscope with digital angiographic capabilities (C-arm or fixed unit). Fluoroscopic imaging and the ability to record and recall all imaging.
- Assorted guidewires of adequate length
- Heparinized saline solution

9.5 Additional Equipment Recommended

- Introducer sheaths
- Power Injector
- Radiopaque ruler with centimeter increments
- Assorted balloon catheters
- Compliant balloon catheters
- Radiopaque contrast media
- Sterile silicone lubricant or sterile mineral oil
- Interventional snare devices
- Coils or Amplatz stents

9.6 MRI Information

Nonclinical testing has demonstrated that the Endurant Stent Graft is MR Conditional. It can be scanned safely in both 1.5 Tesla and 3.0 Tesla magnetic resonance (MR) systems under the following conditions:

- Static magnetic field of 1.5 tesla and 3.0 tesla
- Spatial gradient field ≤ 1000 gauss/cm
- Maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning (or the maximum SAR allowed by the MR System, whichever is less).
- Patients with an Endurant Stent Graft implanted in the abdominal aorta may safely undergo MRI for Normal Mode and First Level Controlled Operating Mode of the MR System, as defined in IEC Standard 60601-2-33.¹

In nonclinical testing, the Endurant Stent Graft produced a temperature rise of less than 0.30° C when normalized to the local specific absorption rate (SAR) for 15 minutes of MR scanning in a 64 MHz whole body transmit coil, which corresponds to a static field of 1.5 tesla. It produced a temperature rise of less than 0.60° C when normalized to the local specific absorption rate (SAR) for 15 minutes of MR scanning in a 3.0 tesla Siemens TrioTim² MR scanner.

MR image quality may be compromised if the area of interest is the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. The image artifact extends approximately 5 mm and 8 mm from the device, both inside and outside the device lumen when scanned in nonclinical testing using the sequence: spin echo and gradient echo, respectively, in a 3.0 tesla Siemens TrioTim (VB 13 Software) MR system with a whole body coil.

¹ IEC 60601-2-33 ED 3.0. MEDICAL ELECTRICAL EQUIPMENT -Part 2-33: Particular requirements for basic safety and essential performance of magnetic resonance equipment for medical diagnosis. Draft (August 10, 2007).

² Siemens and Tim are registered trademarks of Siemens Aktiengesellschaft.

10 IMPLANT INSTRUCTIONS

10.1 Vascular Access and Device Preparation

Correct sizing of the aorta and iliac vessels must be determined before implantation of the bifurcated and iliac stent graft components using contrast-enhanced computer-aided tomography (CT), as well as angiograms of both the iliac arteries and aorta. 3D imaging may also be beneficial. Refer to section 9.2, Recommended Device Sizing. These images should be available for review during the procedure. Vascular instruments and other surgical supplies needed to gain access to the artery should also be available.

To reduce the risk of thromboembolism, it is recommended that the patient be heparinized for the duration of the procedure.

Caution: Do not retract the graft cover of the delivery system until it is accurately placed within the vasculature and ready for deployment.

Caution: Never advance or retract equipment from the vasculature without the use of fluoroscopy.

10.1.1 Vascular Access

- Following aseptic procedure, perform a vascular access at the femoral arteries.
- Place a guidewire in the ipsilateral femoral artery and advance it above the renal arteries.
- From the contralateral side femoral artery, place a second guidewire directed to the abdominal aorta.
- Over this guidewire, place an angiography catheter above the renal arteries.
- Take an angiogram.

Note: There is a possibility that an additional incision might be necessary to access the common iliac artery.

10.1.2 Device Preparation

- Prior to insertion, view the delivery system under fluoroscopy to visualize the radiopaque markers on the stent graft. The radiopaque markers indicate the position of the proximal and distal edges of the graft material.
- Turn the graft cover to align the radiopaque marker on the short stub leg (of the bifurcated component) with the patient's contralateral iliac artery.
- Flush the guidewire lumen with heparinized saline.
- Wet the graft cover of the delivery system to activate the hydrophilic coating

10.2 Delivery Procedure

Medtronic Vascular recommends using an appropriate caliber introducer sheath to perform diagnostic tests.

Warning: To prevent thrombotic problems, a second bolus of IV heparin is recommended before inserting the device.

10.2.1 Introduction of Bifurcated Component

Warning: Do not advance the delivery system without first having placed a guidewire.

- Slowly insert the aortic delivery system.
- Advance over the guidewire so that the proximal most stents and the radiopaque markers are visualized in the target proximal aortic neck (Figure 7).
- Inject contrast media into the abdominal aorta and mark the position of the target location, either on the imaging screen or on the patient's body.
- Adjust the position of the bifurcated stent graft component so that the top edge of the graft fabric is just below the lowest renal artery. (The edge of the graft fabric is 0.5 mm -1.0 mm above the top edge proximal radiopaque markers.)

Note: If the top edge of the graft fabric is to be placed very close to the renal arteries, contrast media may be injected to identify the location of the lower renal artery and verify the position before full deployment.

Caution: Once proximal position has been identified, do not move the patient or imaging equipment, as it may compromise accuracy of stent graft placement.

Caution: The angiographic catheter can be removed prior to deployment. However, if the angiographic catheter is not removed until after deployment, ensure that the tip is straightened (pigtail catheter) with a guidewire before removal so that the stent graft is not pulled down.

Caution: When aligning the position of stent graft, be sure the fluoroscope is angled perpendicularly to the center line of the infrarenal aorta to avoid parallax or other source of visualization error. Some cranial caudal angulation of the I-I tube may be necessary to achieve this, especially if there is anterior angulation of the aneurysm neck.

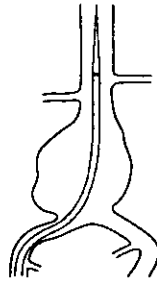


Figure 7: Introduction of Delivery System

10.2.2 Confirm Position

- Ensure that the distal portion of the contralateral stub leg is above the aortic bifurcation and within the aneurysmal sac, and not within the iliac vessel.
- Rotate the handle until the radiopaque marker on the distal-most stent of the contralateral stub leg is aligned with the contralateral iliac artery.

Note: When attempting to rotate the system, if a tip response is not observed, pull back the system and re-position until the intended position is achieved.

10.2.3 Deploy Proximal End of Bifurcated Component

- With 1 hand on the front grip, hold the delivery system stationary.
- With the other hand, slowly withdraw the graft cover by rotating the slider counterclockwise (in the direction of the slider arrow), until the constrained suprarenal stent is released and 2-3 of the covered stents have been fully deployed (Figure 8).
- Use angiography to verify position of the bifurcated component in relation to the renal arteries.
If needed, gently push the entire delivery system proximally or pull distally until the proximal end of the graft material is even with the distal edge of the lowest renal artery.

Note: In the unlikely event of delivery system failure that results in partial stent graft deployment due to graft cover severance, the "handle disassembly" technique may permit successful deployment of the stent graft. Refer to Section 11, Bail-Out Techniques.

Caution: Do not rotate the graft cover during deployment as this may torque the device and cause it to spin on deployment.

Caution: If the graft cover is accidentally withdrawn, the stent graft component will prematurely deploy and may be incorrectly positioned.

Warning: Failure to properly align the radiopaque markers may result in improper deployment of the stent graft.

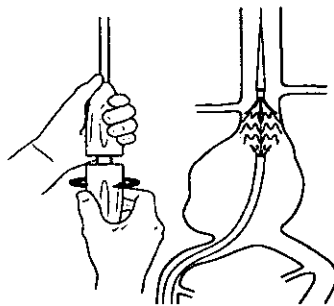


Figure 8: Deploying Proximal End of Bifurcated Component

10.2.4 Deploy Contralateral Leg of Bifurcated Component

- While continuing to hold the delivery system stationary with 1 hand on the front grip, slowly rotate the slider counterclockwise until the contralateral leg is released from the delivery sheath (Figure 9).

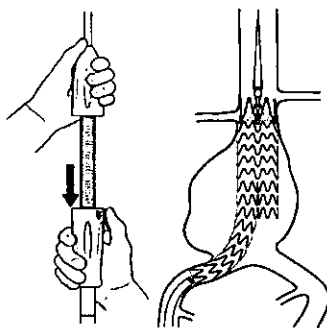


Figure 9: Deploy the Contralateral Leg

10.2.5 Release Proximal End of Suprarenal Stent

- Use angiography to verify the position of the bifurcated component in relation to the renal arteries.
- Continue to hold the Endurant Delivery System stationary with 1 hand on the front grip.
- With the other hand, rotate the back-end wheel clockwise (in the direction of the arrow), moving the tapered tip forward to release the proximal end of the suprarenal stent (Figure 10).
- Observe the release of the suprarenal stent under fluoroscopy and continue turning the back-end wheel until it is completely clear of the delivery system spindle.

Note: In the unlikely event that the proximal end of the suprarenal stent cannot be released, refer to Section 11, Bail-Out Techniques.

Caution: In the unlikely event that the back-end wheel separates during wheel rotation, reassemble the wheel. Refer to Section 11, Bail-Out Techniques, if appropriate.

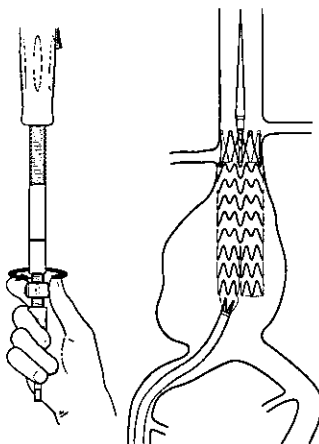


Figure 10: Release Proximal End of Suprarenal Stent

10.2.6 Deploy Distal End of Bifurcated Component

- Either continue to rotate the slider counterclockwise or while holding the front grip of the delivery system stationary, use thumb to pull the trigger on the slider and pull the slider back all the way to finish deploying bifurcated component.
- Withdraw the graft cover until the distal stent of the ipsilateral limb is completely deployed (Figure 11).

Note: Retract the graft cover past the flexible stent stop tip (approximately 10 mm) to ensure that the graft cover edge does not disturb the graft position during forward advancement of the catheter for tip recapture.

Caution: When using the trigger to rapidly deploy the stent graft, be sure to hold the delivery system stationary. Do not rotate the delivery system during stent graft deployment.

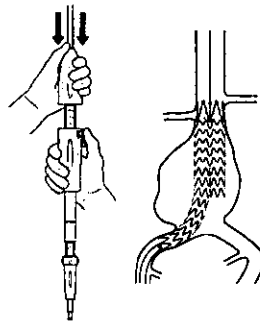


Figure 11: Deploy Distal End of Bifurcated Component

10.2.7 Recapture Spindle in Tapered Tip

- Continue to hold the delivery system stationary with 1 hand on the front grip.
- Confirm the spindle has fully separated from the suprarenal stent; gently torque the delivery system if it has not fully separated.
- Gently torque and push the entire delivery system approximately 3 cm proximally so that the tapered tip and spindle are completely clear of the suprarenal stent.
- With the other hand, rotate the back-end wheel counterclockwise (opposite the direction of the arrow) recapturing the spindle in the tapered tip (Figure 12).
- Observe the recapture of the spindle within the sleeve of the tapered tip under fluoroscopy.
- Continue turning the back-end wheel counterclockwise until the spindle has been completely recaptured and the back-end wheel is at the bottom (Figure 12).

Note: When pushing the delivery system forward, be careful not to displace the distal end of the ipsilateral limb.

Note: Ensure that the suprarenal stent is fully disengaged from the spindle before pushing the delivery system forward.

Note: If the spindle catches on the suprarenal stent during advancement, completely advance the back-end wheel clockwise. Using a gentle in-and-out motion with the delivery system, rotate the delivery system until the spindle slips past the suprarenal stent. Then continue with the withdrawal process.

Caution: Make sure to stop rotating the back-end wheel when you reach the bottom of the back-end screw gear.

Warning: Failure to adequately advance the delivery system to recapture the spindle can result in the trapping of a suprarenal crown within the tapered tip sleeve. This will alter the proximal landing zone during delivery system withdrawal.

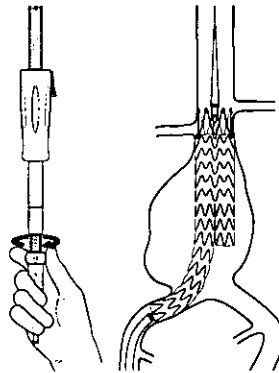


Figure 12: Recapture Spindle in Tapered Tip

10.2.8 Remove Delivery System

- Continue to hold the delivery system stationary with 1 hand on the front grip and the other hand on the slider.
- Gently torque and withdraw the delivery system until the spindle is retracted into the fabric portion of the stent graft.
- Pull back the slider trigger and hold the slider stationary while bringing the front grip to the slider (Figure 13).
- Use continual fluoroscopy and watch the top of the bifurcated component while slowly pulling back the tapered tip into the graft cover of the delivery system.
- Gently remove the delivery system. Use fluoroscopy to ensure that the bifurcated component does not move during withdrawal.

Note: Maintain vessel access until all stent graft components are in place.

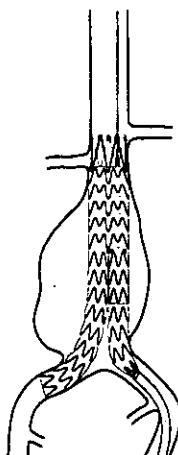


Figure 13: Remove Delivery System

10.2.9 Deploy Contralateral Limb Component

- a. Prepare the iliac stent graft system as described in Section 10.1.2, Device Preparation.
- b. On the patient's contralateral side, insert a guidewire through the contralateral leg and aortic neck of the previously placed bifurcated component.
- c. Place the delivery system over the guidewire and into the contralateral leg of the bifurcated component.
- d. Insert the contralateral limb component into the contralateral leg of the bifurcated component. The proximal radiopaque marker of the contralateral limb component should be aligned to the radiopaque marker at the bifurcation of the bifurcated component.
- e. Ensure there is a 3-stent overlap (Figure 14).

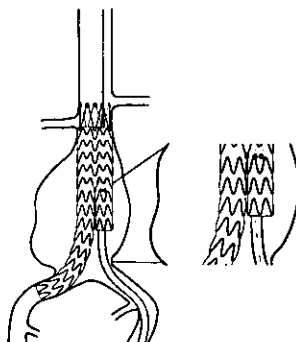


Figure 14: 3-Stent Overlap

- f. With 1 hand on the front grip, hold the delivery system stationary.
- g. With the other hand, slowly withdraw the graft cover by rotating the slider counterclockwise.
- h. At any point, pull slider trigger and pull the slider back all the way to finish deploying the contralateral limb component (Figure 15).
- i. Remove the delivery system as described in Section 10.2.8.

Note: In the unlikely event of delivery system failure that results in partial stent graft deployment, the "handle disassembly" technique may permit the successful deployment of the stent graft component. Refer to Section 11, Bail-Out Techniques.

Caution: Do not rotate the delivery system during deployment.

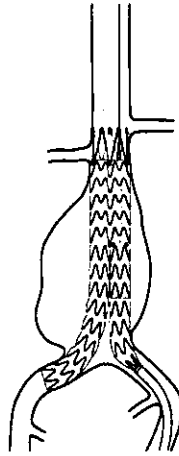


Figure 15: Deploy Contralateral Limb Component

10.2.10 Iliac or Aortic Extension Components

- If an aortic extension component is needed, ensure that there is a minimum 3-stent overlap between the aortic extension component and the bifurcated component.
- Follow the bifurcated component deployment process, except rotate the handle to open the extension component entirely before releasing the proximal end of the suprarenal stent of the aortic component.
- If an iliac extension component is needed, ensure that there is a minimum 3-stent overlap between the iliac extension component and the component it is inserted into.
- Follow the contralateral limb component deployment process described in Section 10.2.9.

10.2.11 Smoothing Stent Graft Fabric and Modeling Stent Graft

The Reliant Stent Graft Balloon Catheter (packaged separately) can be used to assist in stent graft implantation by modeling the covered portion of the stent graft and removing wrinkles and folds from the graft material, as needed. Use the balloon catheter to model the proximal and distal seal zones as well as any overlapping connection (or junction) areas between the stent graft components. Sub-optimal expansion of the self-expanding stent graft components may also be improved by use of the balloon catheter. Refer to the Reliant Stent Graft Balloon Catheter IFU for specific instructions.

Note: The Reliant Stent Graft Balloon Catheter is recommended for use with the Endurant Stent Graft System. Data is not available for the use of other balloon catheters in remodeling stent grafts.

Note: Care should be taken when inflating the balloon, especially with calcified, tortuous, stenotic, or otherwise diseased vessels. Inflate slowly. It is recommended that a backup balloon be available.

Caution: Over inflation of balloon can cause graft tears and/or vessel dissection or rupture.

Warning: When expanding a vascular prosthesis, there is an increased risk of vessel injury and/or rupture, and possible patient death, if the balloon's proximal and distal radiopaque markers are not completely within the covered (graft fabric) portion of the prosthesis.

Warning: Do not use the Reliant Stent Graft Balloon Catheter in the treatment of dissections.

10.2.12 Seal Entry Sites

- Remove the introducer and the guidewire.
- Repair the entry site with standard closure technique.

10.2.13 Verify Placement and Seal

- At the completion of the procedure, perform angiography to assess the stent graft for proximal and distal endoleaks and to verify position of the implanted stent graft in relation to the aneurysm and renal arteries.
- Leaks at the attachment or connection sites should be treated using a balloon catheter to remodel the stent graft against the vessel wall.
- Major leaks that cannot be corrected by re-balloonning may be treated by adding aortic or iliac extension components to the previously placed stent graft components.

Caution: Any leak left untreated during the implantation procedure must be carefully monitored after implantation.

11 BAIL-OUT TECHNIQUES

In the unlikely event of a delivery system failure, the following bail-out techniques may be used.

11.1 Screw Gear Handle Disassembly

If partial stent graft component deployment due to graft cover severance occurs, the screw gear handle disassembly technique may permit successful deployment of the stent graft.

- a. Pull back the trigger and fully retract the slider.
- b. Stabilize the delivery system.
- c. Insert the tips of a pair of hemostats into each of the screw gear handle disassembly ports on the front grip.
- d. Disengage the front grip from the screw gear by pressing the tips of the hemostats into the handle disassembly ports simultaneously advancing the front grip away from the screw gear.
- e. Advance the front grip until it fully clears the screw gear.
- f. Separate the screw gear halves in order to identify the location of graft cover severance.
- g. Manually retract the graft cover with your fingers or with hemostats until the stent graft is fully deployed.
- h. Follow the instructions for tip capture deployment and delivery system removal.

11.2 Ballooning

If the captured proximal tip of the suprarenal stent cannot be deployed and the back-end wheel section still works, the ballooning technique may permit successful deployment of the suprarenal stent.

- a. Use a compliant or semi-compliant balloon (Reliant Balloon recommended).
- b. Insert the balloon and move it to the bifurcated component aortic section.
- c. Inflate the balloon inside the stent graft to vessel size to stabilize stent graft.
- d. Follow the instructions for tip capture deployment and delivery system removal.

11.3 Back-End Handle Disassembly

If no or partial deployment of the proximal end of the suprarenal stent occurs due to back-end wheel failure, the back-end handle disassembly technique may permit the successful deployment of the suprarenal stent.

- a. Use hemostats to depress the exposed tabs to disassemble the back-end wheel.
- b. Insert the tips of hemostats into each of the rear handle disassembly ports.
- c. Disengage the rear handle by pressing the tips of the hemostats into the handle disassembly ports simultaneously retracting the rear handle from the delivery system.
- d. Stabilize the delivery system.
- e. Manually push up the back-end T-tube to deploy the tip captured suprarenal stent.
- f. Manually pull back the back-end T-tube to recapture the tapered tip after deployment.
- g. Follow the instructions for delivery system removal.
- h. Hold the back-end T-tube so that it remains retracted and the tapered tip recaptured during delivery system removal.

11.4 Snare the Tapered Tip

If the back-end handle disassembly technique is unsuccessful due to an excessively high deployment force, a snare the tapered tip technique may permit successful deployment of the suprarenal stent.

- a. Use a snare device.
- b. Advance the snare device to the delivery system tapered tip section through upper torso access (i.e., brachial).
- c. Utilize fluoroscopy to snare the edge of the delivery system tapered tip.
- d. Stabilize the delivery system, especially the back-end section.
- e. Pull the snare device to separate the suprarenal stent from the tip capture.
- f. Manually pull back the back-end T-tube to recapture the tapered tip after deployment.
- g. Follow the instructions for delivery system removal.
- h. Ensure that the back-end T-tube remains retracted and the tapered tip recaptured during delivery system removal.

12 FOLLOW-UP IMAGING RECOMMENDATIONS

12.1 General

Current imaging of stent graft patients includes abdominal X-ray and CT, with and without contrast medium. Alternative imaging modalities such as magnetic resonance imaging should be used in patients with impaired renal function or intolerance to contrast media.

Imaging should be decided based upon the physician's clinical assessment of the patient pre- and post-implantation of the stent graft. After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. Annual imaging is recommended, including 1) abdominal radiographs to examine device integrity (stent fracture, separation between bifurcated device and proximal cuffs or limb extensions, if applicable), and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.

12.2 X-ray

Abdominal X-rays should be used to assess the presence of stent graft fracture. Four-view kidney, ureter, bladder (KUB) X-rays should be taken. Posterior/anterior (PA) and lateral images are recommended for visualization of the stent graft. Ensure the entire device is captured on images for device assessment.

12.3 CT with Contrast

Contrast-enhanced CT should be used to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, stent graft patency, AAA size, occlusion of branch vessels, and endoleak (including source and type if present).

A pre-contrast scan of 5 mm thick slices is suggested to determine if there are calcifications or areas where metal artifacts may be misinterpreted as endoleak. An arterial phase with ≤ 3 mm slice thickness and overlapping images with coverage from the celiac artery to the external iliac is recommended. In aneurysms that are not shrinking and have no apparent endoleak or fixation problems, a late venous phase scan may be performed. The venous phase scan may also be performed with thicker collimation (5 mm). It is recommended that the source data set be archived in case specialized evaluation is needed later (volume measurements, 3-dimensional reconstruction, or computer-aided measurement software). If the aneurysm is not shrinking by more than 5 mm within the first year, volume measurements may be obtained as a more sensitive indicator of AAA size using 3-dimensional software. The physician will determine the requirement pre-operative care for patients with allergies to contrast.

12.4 Non-Contrast CT

For patients with impaired renal function or those who are allergic to contrast medium, a spiral CT without contrast may be considered to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, occlusion of vessels, and size of the AAA with diameter and volume measurements.

12.5 Duplex Ultrasound

For patients with impaired renal function or those who are allergic to contrast medium, a color-duplex ultrasound may be considered to assess size of AAA with diameter, endoleaks, and stent graft occlusion and stenosis.

12.6 MRI or MRA

Patients with impaired renal function, ie, renal insufficiency, may also be considered for magnetic resonance imaging or angiography (MRI, MRA) in facilities that have expertise in this area. Artifact may occur related to the stent, and care should be used to insure adequate imaging of the outer aneurysm wall to assess AAA size. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed. Additional MRI technical information can be obtained at <http://www.medtronic.com/EndurantMRI>. Specific information on MRI can be found in Section 9.6, MRI Information.

12.7 Imaging Tests

Refer to the table below for the recommended follow-up imaging schedule after stent graft implant.

Table 33: Imaging Recommendations

Interval	Angiogram	CT ¹ [Contrast & Non-Contrast]	Abdominal Radiographs
Pre-Procedure		X	
Procedural	X		
1 Month		X	
12 Months (annually thereafter)		X	X

¹ CT evaluation may include "3-phase technique," volume studies, 3-D reconstruction, or computer-aided measurements.

12.8 Supplemental Imaging

Note: Additional radiological imaging may be necessary to further evaluate the stent graft in situ based on findings revealed by one (1) of the surveillance programs. The following recommendations may be considered.

- If there is evidence of poor or irregular position of the stent graft, severe angulation, kinking, or migration of the stent graft on abdominal X-rays, a spiral CT should be performed to assess aneurysm size and the presence or absence of an endoleak.
- If a new endoleak or increase in AAA size is observed by spiral CT, adjunctive studies such as 3-D reconstruction or angiographic assessment of the stent graft and native vasculature may be helpful in further evaluating any changes of the stent graft or aneurysm.
- Spiral CT without contrast, MRI or MRA may be considered in select patients who cannot tolerate contrast media or who have renal function impairment. For centers with appropriate expertise, gadolinium or CO2 angiography may be considered in patients with renal function impairment requiring angiographic assessment.

13 ADDITIONAL SURVEILLANCE AND TREATMENT

Additional endovascular repair or open surgical aneurysm repair should be considered for patients with evidence of suboptimal stent graft fixation, proximal endoleak, distal endoleak, junction endoleak, unknown origin of persistent perigraft flow, or increase in AAA size > 5mm.

14 DISCLAIMER OF WARRANTY

ALTHOUGH THE MEDTRONIC VASCULAR ENDURANT STENT GRAFT AND DELIVERY SYSTEM, HEREFTER REFERRED TO AS THE 'PRODUCT', HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC, INC., MEDTRONIC VASCULAR, INC. AND THEIR RESPECTIVE AFFILIATES, (COLLECTIVELY "MEDTRONIC") HAVE NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

15 DEVICE REGISTRATION

The Endurant Stent Graft System is packaged with additional specific information which includes:

- **Temporary Device Identification Card** that includes both patient and stent graft information. Physicians should complete this card and instruct the patient to keep it in their possession at all times. The patients should refer to this card anytime they visit additional health practitioners, particularly for additional diagnostic procedures (e.g. MRI). This temporary identification card should only be discarded when the permanent identification card is received.
- **Device Tracking Form** to be completed by the hospital staff and forwarded to Medtronic for the purposes of tracking all patients who received an Endurant Stent Graft (as required by Federal Regulation). The hospital's submission of the device tracking form to Medtronic is also required for a patient to receive the permanent identification card.

Upon receipt of the device tracking form, Medtronic will mail the patient a **permanent device identification card**. This card includes important information regarding the implanted stent graft. Patients should refer to this card anytime they visit health practitioners, particularly for any diagnostic procedures (e.g., MRI). Patients should carry this card with them at all times. If a patient does not receive their permanent device identification card, or requires changes to the card, call 1-800-551-5544. In addition a patient information booklet (PIB) will be provided to the physicians during training and additional copies will be available upon request. The PIB will also be available online on the Medtronic website (www.medtronic.com). This booklet provides patients with basic information on abdominal aortic aneurysms and endovascular repair therapy.

MANUFACTURER:
MEDTRONIC, INC.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
www.medtronic.com

US CUSTOMER SERVICE/PRODUCT INQUIRIES:
Tel: (800) 961-9055
Fax: (800) 929-2133

© 2010 Medtronic, Inc.

Protected by one or more of the following United States patents: 6,306,141; 6,911,039; 7,105,016; 7,264,632; and 7,655,034.

M720548B001

Rev 1B